

EXHIBIT D

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SUPERIOR COURT OF NEW JERSEY

LAW DIVISION

ATLANTIC COUNTY

MASTER CASE 6341-10

CASE NO. 291 CT

- - -

IN RE:

PELVIC MESH/GYNECARE

LITIGATION

- - -

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Friday, December 20, 2013

VOLUME III

- - -

Continued videotaped deposition of JAMES C. HART, M.D., held at RIKER DANZIG, SCHERER, HYLAND & PERRETTI, L.L.P., Headquarters Plaza, One Speedwell Avenue, Morristown, New Jersey, commencing at approximately 9:54 a.m., before Rosemary Locklear, a Registered Professional Reporter, Certified Realtime Reporter, Certified Court Reporter (NJ License No. 30XI00171000), and Notary Public.

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1 ALSO PRESENT:

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3 CHRISTOPHER CAMPBELL, Video Operator

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1 I N D E X

2

3 WITNESS

PAGE

4

5 JAMES C. HART, M.D.

6

7 By Mr. Slater 612, 918, 970

8 By Mr. Sheridan 809

9 By Mr. Snell 810, 961, 979

10

11 - - -

12

13 EXHIBIT INDEX

14 NUMBER

MARKED

15

16 T-1340A 2-page copy of document dated 628

3/22/10 entitled "Appendix 6,

17 Amendment and Administrative

Change Approval Form,"

18 ETH.MESH.00408092 -

ETH.MESH.00408093

19

20 T-1341A 55-page copy of document dated 628

3/22/10 entitled "A Prospective,

21 Multi-centre Study to Evaluate

the Clinical Performance of the

GYNECARE PROLIFT+M Pelvic Floor

22 Repair System as a Device for

Pelvic Organ Prolapse,"

23 ETH.MESH.00408099 -

ETH.MESH.00408153

24

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1		EXHIBIT INDEX (Continued)	
2	NUMBER		MARKED
3			
4	T-1342A	3-page copy of document entitled "Final Protocol,"	654
5		ETH.MESH.00408351 -	
6		ETH.MESH.00408353	
7	T-1343A	51-page copy of document dated 8/10/07 entitled "A Prospective,	654
8		Multi-centre Study to Evaluate	
9		the Clinical Performance of the	
10		GYNECARE PROLIFT+M Pelvic Floor	
11		Repair System as a Device for	
12		Pelvic Organ Prolapse,"	
13		ETH.MESH.00408354 -	
14		ETH.MESH.00408404	
15	T-1344A	6-page copy of document entitled "Gynecare TVT,"	661
16		ETH.MESH.03427878 -	
17		ETH.MESH.03427883	
18	T-1345A	2-page copy of memo dated 12/2/99 to R. Rousseau from	674
19		Thomas A. Barbolt, Ph.D.,	
20		D.A.B.T., ETH.MESH.00220335 -	
21		ETH.MESH.00220336	
22	T-1346A	1-page copy of document dated 5/14/01 entitled "Target Sheet,"	675
23		ETH.MESH.00220297	
24	T-1347A	6-page copy of document entitled "Gynecare TVT,"	752
25		ETH.MESH.00339437 -	
		ETH.MESH.00339442	
	T-1348A	8-page copy of document entitled "The Leader in Midurethral Sling	761
		Devices for the Treatment of	
		SUI," ETH.MESH.00658058 -	
		ETH.MESH.00658065	

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1	EXHIBIT INDEX (Continued)		
2	NUMBER		MARKED
3			
4	T-1349A	5-page copy of document entitled	769
5		"Make Data and Safety Your	
6		Choice," ETH.MESH.01186068 -	
7		ETH.MESH.01186072	
8	T-1350A	2-page copy of document entitled	779
9		"Gynecare TVT Family of Products	
10		Tension-free Support for	
11		Incontinence," ETH.MESH.02237103	
12		- ETH.MESH.02237104	
13	Hart D-1	56-page copy of document	840
14		entitled "Placeholder,"	
15		ETH.MESH.03361293	
16	Hart D-2	9-page copy of article dated	846
17		1/12 entitled "One-Year	
18		Objective and Functional	
19		Outcomes of a Randomized	
20		Clinical Trial of Vaginal Mesh	
21		for Prolapse"	
22			
23			
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1	EXHIBITS PREVIOUSLY REFERENCED			
2				
3	NUMBER	PAGE	NUMBER	PAGE
4				
5	243	613		
6	T-1225	616		
7	T-3142	691		
8	T-1338	734		
9	T-1333	737		
10	T-1312	835		
11	T-1311	837		
12	T-1317	850		
13	T-858	858		
14	T-1324	868		
15	T-1323	863		
16	409	873		
17	T-1303	893		
18	T-1329	898		
19	T-1337	901		
20	T-1330	915		
21	T-1331	915		
22	T-1332	915		
23	858	966		
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1 VIDEO OPERATOR: We are now on the record.

2 My name is Christopher Campbell. I'm a
3 videographer for Golkow Technologies.

4 Today's date is December 20th, 2013, and
5 the time is 9:54. This deposition is being held in
6 Morristown, New Jersey, In Re: Pelvic Repair
7 Systems, for the Superior Court of New Jersey,
8 Atlantic County. The deponent is Dr. James Hart.

9 Counsel will be noted on the stenographic
10 record. Our court reporter is Rosemary Locklear, and
11 she will now swear in the witness.

12 JAMES C. HART, M.D., having been duly
13 sworn, was examined and testified as follows:

14 EXAMINATION (Continued)

15 BY MR. SLATER:

16 Q. All right. Good morning, Dr. Hart.

17 A. Morning.

18 Q. I gave you some instructions and
19 explanation about a deposition proceeding when we
20 started this deposition. Any need for me to go over
21 any of that with you?

22 A. No.

23 Q. Terrific. In front of you is Exhibit --
24 let me start over.

25 In front of you is an exhibit which was

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1 marked as Exhibit 243, titled "biocompatibility is
2 the science of living better."

3 MR. SLATER: All clipped? I'll start
4 over.

5 BY MR. SLATER:

6 Q. In front of you is Exhibit Number 243,
7 which is a sales aid titled "biocompatibility is the
8 science of living better" and has to do with the
9 Prolift+M.

10 Do you see that in front of you?

11 A. I do.

12 Q. Right at the very bottom of the first page
13 there's a sentence that says, designed for improved
14 patient comfort, Prolift+M gives you a more advanced
15 graft so your patient gets more with less.

16 Do you see that?

17 A. I do.

18 Q. If you could now turn to the page that's
19 actually third from the end. There's an 84 at the
20 end of the Bates number.

21 A. Uh-huh.

22 Q. This says at the top, Prolift+M, the graft
23 that keeps caring for your patient after surgery.

24 See that?

25 A. I do.

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1 Q. And then if you go further down, there's a
2 paragraph that starts out, using the new Gynecare
3 Prolift+M pelvic floor repair system.

4 You see that paragraph?

5 A. Uh-huh.

6 Q. And it talks about demonstrated excellent
7 results with this device. Do you see that? At the
8 very end of that paragraph it says, have demonstrated
9 excellent results.

10 Do you see that?

11 A. Yeah.

12 Q. And then it talks about what those
13 excellent results have been and there's three bullet
14 points. I'd like to go through them one at a time
15 with you.

16 The first one, a pronounced reduction in
17 inflammation and improved integration into
18 surrounding tissue; the second one, reduced foreign
19 body response; and the third one, less fibrosis than
20 traditional grafts.

21 See where I'm reading?

22 A. I do.

23 Q. And, in essence, in this sales aid that
24 would be provided to physicians the doctors are being
25 told that with the Prolift+M they can expect these

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1 improved characteristics.

2 That's what the words say; correct?

3 A. Designed for, yeah.

4 Q. If you go to the next page, at the top it
5 talks about, again, the material science now and at
6 the top it talks about in your hands, talking to the
7 physician, and then it talks about in your patient's
8 body what it's designed to do.

9 Do you see that on the top right?

10 A. Yes.

11 Q. And in the patient's body the doctors are
12 told, resist wound contraction, otherwise known as
13 shrinkage, offer improved tissue integration, result
14 in softer, more supple tissue.

15 See that?

16 A. Yes.

17 Q. And, again, this type of a document would
18 be reviewed by medical affairs to make sure that any
19 of the representations that are made as to the
20 clinical attributes of the device are accurate;
21 correct?

22 A. Correct.

23 Q. And medical affairs is required to make
24 sure that claims are not made in a document like this
25 unless they can be verified by data; correct?

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1 MR. SNELL: Form.

2 THE WITNESS: Oftentimes, will refer to
3 data. But they -- they are held accountable to
4 review for accuracy and scientific accuracy.

5 BY MR. SLATER:

6 Q. So, in other words -- well, I'll rephrase.
7 And medical affairs as part of its
8 oversight responsibilities has to make sure that any
9 claims made in this type of a document have
10 scientific accuracy; correct?

11 A. Yeah, that's their job. Yeah.

12 Q. Okay. Let's go to the next document,
13 which -- and we're done with that one.

14 What I've -- what I've handed you is a
15 document titled "Postmarket Surveillance Study," and
16 it was marked at previous depositions as Plaintiffs'
17 Exhibit 1225 and also at Brian Kanerviko's deposition
18 as Exhibit 8. You can see the little copies of the
19 stickers there.

20 Do you see that at the bottom?

21 A. I do.

22 Q. And what this is is Ethicon's response to
23 the FDA in response to the 522 Order for the Prolift
24 and Prolift+M.

25 And that's a process you were involved

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1 with, to some extent; correct?

2 A. I had visibility to, yeah.

3 Q. And what I'd like you to do now is I'd
4 like to ask you to turn to Page 19. Page 19, there's
5 a table which provides information about mesh
6 exposures seen in patients that went through the
7 Prolift+M clinical study.

8 Do you see that in front of you?

9 A. Let me just have a look here.

10 Okay. Yes.

11 Q. The table actually is titled "Table 2.e:
12 Mesh exposure rate and severity of incidence over
13 time," and it then gives information about the
14 various patients who had exposures and what treatment
15 was provided and essentially when these occurred.

16 Do you see that?

17 A. Yeah. Uh-huh.

18 Q. The table shows that there were a total of
19 19 mesh exposures, and it talks about what treatment
20 the patients had. It says three of them had medical
21 treatment.

22 That would mean estrogen cream or
23 something non-surgical, non-procedural; correct?

24 A. I would assume so, yeah.

25 Q. Then it talks about minor outpatient

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1 surgery. That would be -- there's actually an
2 asterisk. It says, not possible to differentiate
3 between intra-office and outpatient surgery.

4 But it means somebody was not actually
5 admitted to the hospital, even though a surgical
6 procedure was performed; correct?

7 A. Correct.

8 Q. And it says 10 of the 19 mesh exposures
9 were treated surgically, whether in the office of the
10 doctor or at a hospital; correct?

11 MR. SNELL: Form. You meant 11.

12 MR. SLATER: I'll ask it differently.

13 MR. SNELL: You miscounted. That's the
14 only reason why. It's 11, not 10.

15 MR. SLATER: It says 10 right there.

16 MR. SNELL: Okay. I heard you.

17 MR. SLATER: I'll ask the question again.

18 BY MR. SLATER:

19 Q. So what this is basically -- rephrase.

20 So this is telling us that 10 of the
21 people who had exposures had a surgical procedure,
22 whether it was in the office or in the hospital on an
23 outpatient basis, to treat their exposures. That's
24 what this table shows us; correct?

25 A. Yes. It didn't necessarily have to be a

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1 hospital but they -- they had surgical procedures in
2 the office or another facility.

3 Q. It could be a hospital, it could be a
4 surgicenter, something like that.

5 A. Correct.

6 Q. That's what you're referring to?

7 A. Yes.

8 Q. Okay. Four of the patients had inpatient
9 surgery. And that would mean the patient was
10 actually admitted to a hospital to have a procedure,
11 an operative procedure, to treat the exposure;
12 correct?

13 A. That would seem reasonable. I presume
14 that's what they meant.

15 Q. That would seem reasonable because the
16 other outpatient surgery means they were on an
17 outpatient basis. The only one left is inpatient,
18 and that's when you're admitted; correct?

19 A. Yes.

20 Q. Okay. So we know that 14 of the 19 were
21 treated either in an office or in an outpatient basis
22 or in a hospital as an inpatient with a surgical
23 procedure for their exposures.

24 That's what this documents; correct?

25 A. Yes.

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1 Q. And any patient who had a surgical
2 procedure, whether in a doctor's office, whether in
3 an outpatient setting, whether as an inpatient in a
4 hospital, none of those would be characterized as
5 mild, by definition, because a procedure was actually
6 performed to treat the exposure; correct?

7 MR. SNELL: Form.

8 THE WITNESS: Mild what? I don't --

9 BY MR. SLATER:

10 Q. You would not refer to an exposure as a
11 mild exposure if it required a surgical procedure,
12 whether in a doctor's office, at a surgicenter or at
13 a hospital; correct?

14 MR. SNELL: Same objection.

15 THE WITNESS: Not necessarily, I don't
16 think.

17 I mean, I would just -- it's a -- it's a
18 spectrum of how do you want to characterize. I think
19 it's better rather than using an adjective that's so
20 nonspecific like "mild," I would say they -- they
21 required surgical intervention for their treatment
22 and --

23 BY MR. SLATER:

24 Q. If someone -- well, rephrase.

25 As I'm asking you now, if you were given

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1 the option to describe these exposures where an
2 operative procedure was performed to treat them as
3 either mild, moderate or severe, you would not choose
4 the word "mild," in light of the fact that they had
5 a --

6 A. Well, I'm not sure --

7 Q. -- operative procedure; correct?

8 A. I'm not sure that that's true. If they had
9 a -- if they had a tiny erosion but that was -- the
10 physician felt it was best treated with a minor
11 procedure best done in a facility, then it still
12 could be, in my opinion, a mild complication. I
13 mean, it's -- it's -- you know, it's just a
14 definition. How do you want to define mild?

15 Q. Are you aware that you've already
16 testified that if a mesh exposure occurs and there's
17 a revision procedure, that that's a serious adverse
18 event?

19 A. It is a serious adverse event. It's a
20 different -- that's a definition based on sort of
21 clinical research definitions.

22 Q. Turn to the prior page, if you could.

23 At the bottom of the table on the
24 cumulative rate and severity of adverse events from
25 this Prolift+M study at the very bottom there are

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1 definitions of mild, moderate and severe.

2 Do you see that?

3 A. So, again, that's -- so that --

4 Q. I'm only asking, do you see those
5 definitions that your company supplied in this
6 document?

7 A. Yes.

8 Q. Okay. And it defines mild -- rephrase.

9 This set of definitions defines mild as
10 awareness of a sign or symptom that does not
11 interfere with the subject's usual activity or is
12 transient, resolved without treatment and with no
13 sequelae.

14 Do you see that?

15 A. I do.

16 Q. So, by definition, if you needed to have
17 an operative procedure, it would not be mild.

18 A. So in a -- in the -- in the realm of
19 clinical research, when you define adverse events
20 as -- so there's mild, moderate and severe. That's
21 different than serious and non -- and not serious.
22 Those are two different kinds of definitions. And,
23 yes, in clinical research this definition applies for
24 the -- for the -- or this definition of mild is
25 accurate.

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1 Q. So under the definition of mild that's
2 used in the clinical research context, a -- a mesh
3 exposure would not be termed mild if an operative
4 procedure was performed to treat it; correct?

5 MR. SNELL: Form.

6 THE WITNESS: So it would not be
7 considered mild but not because it required an
8 operative procedure but, rather, it fit this
9 definition.

10 Serious is because it requires -- you
11 would call it serious because it required an
12 intervention.

13 BY MR. SLATER:

14 Q. This is what I'm asking you. Because
15 you've talked about adverse events being a different
16 area, so I'm going to -- I'm not talking about that
17 anymore.

18 A. Okay.

19 Q. In clinical research, which this document
20 is talking about clinical research, when an adverse
21 event in the context of a clinical research study is
22 described --

23 A. Right.

24 Q. -- you would not describe that adverse
25 event as mild if an operative procedure was performed

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1 to treat the complication, in this case, a mesh
2 exposure.

3 MR. SNELL: Form.

4 THE WITNESS: I think that's broadly true.

5 MR. SLATER: Okay.

6 BY MR. SLATER:

7 Q. Now, what I'd like to do is go back now to
8 the table that we talked about earlier on Page 19.

9 On Page 19 just above the table where we
10 established 14 of 19 mesh exposures were treated with
11 an operative procedure -- right?

12 A. Uh-huh.

13 Q. Just above that it says, the overall
14 incidence of mesh exposure to 36 months was 14.8
15 percent, with the majority of the mesh exposures
16 occurring in the first 12 months. And then it says,
17 and with the exception of two exposures, all were
18 considered to be mild in nature.

19 Do you see that?

20 A. Uh-huh.

21 Q. Based on the definition we've discussed in
22 a clinical study like this, you would not want to
23 describe a mesh exposure as mild where an operative
24 procedure had to be performed to treat it; correct?

25 A. So I think --

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1 MR. SNELL: Form.

2 THE WITNESS: I think they're talking
3 about two different things. They're talking about
4 sort of the -- the severity of the exposure, so there
5 was an exposure so, therefore, it's a serious adverse
6 event, and you would not classify it in clinical
7 research as a mild adverse event.

8 You -- they're just -- I think they're
9 just putting an adjunct against what was the level of
10 concern or how -- how bad did the -- did the
11 physician think the exposure was as an exposure.
12 That's -- I think it's a different thing.

13 BY MR. SLATER:

14 Q. Well --

15 A. But I --

16 Q. -- let me ask it this way: Four of the
17 women had to be admitted to a hospital to have an
18 operative procedure in the hospital.

19 Nobody could reasonably describe those as
20 mild exposures, when a woman had to be admitted to a
21 hospital; correct?

22 A. I don't know. It depends on why they had
23 to be admitted.

24 Q. Let's come back to what you said, Dr.
25 Hart.

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1 We've already established that in the
2 clinical study context --

3 A. Right.

4 Q. And this is the clinical study context;
5 right?

6 A. This table is, yes.

7 Q. You would not want to describe a mesh
8 exposure as mild if a surgical procedure had to be
9 performed to treat it; correct?

10 MR. SNELL: Form.

11 THE WITNESS: I don't know that to be
12 true. I mean, depends on -- I mean, within the
13 clinical research definition of mild, it's not mild.
14 I agree to that. No question.

15 If you -- if you talk to a urogynecologist
16 who's taking care and intervening upon a particular
17 erosion or exposure, you know, you would say was that
18 a mild, moderate or severe exposure, they would
19 probably not -- they're not going to be thinking in
20 clinical research definition terms, I don't think.

21 So they -- if you -- if you had a woman
22 that required a relatively minor procedure but she
23 had other co-morbidities, you may want to admit her
24 to the hospital. I don't know why they were
25 admitted. So I don't think it necessarily correlates

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1 with the severity or the -- you know, the difficulty
2 of the exposure or the care of the exposure.

3 MR. SLATER: Rosemary, could you just read
4 me his answer slowly and I'll tell you when to stop
5 and I'll tell you where I'm moving to strike from.

6 (The court reporter read the requested
7 portion of the record.)

8 MR. SLATER: You could stop.

9 Move to strike from "if you talk" forward.

10 BY MR. SLATER:

11 Q. The context of this presentation and this
12 information is clinical research; right? The
13 Prolift+M study was a clinical research study?

14 A. It was.

15 Q. And in that context, as the term "mild" is
16 defined, you would not define a mesh exposure as mild
17 if a surgical procedure had to be performed to treat
18 it; correct?

19 A. Correct.

20 MR. SNELL: Form.

21 BY MR. SLATER:

22 Q. And this was information that your company
23 provided to the FDA in response to the 522 Order;
24 correct?

25 A. I believe so, yes. Yes, it is.

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1 Q. Okay. Okay. We can put that aside.

2 (Exhibit T-1340A was marked for
3 identification.)

4 (Exhibit T-1341A was marked for
5 identification.)

6 MR. SLATER: Burt, this is for Dr. Hart.

7 MR. SNELL: Thank you.

8 MR. SLATER: This is for you.

9 MR. SNELL: Thank you.

10 MR. SLATER: Thomas. Okay.

11 BY MR. SLATER:

12 Q. Dr. Hart, what I've provided you is two
13 exhibits, and they go together.

14 Exhibit 1340 is a set of signatures and
15 1341 is the document to which the signatures apply,
16 which is the final, final version of the protocol for
17 the Prolift+M clinical study.

18 Do you see those documents in front of
19 you?

20 A. Uh-huh. Yes.

21 Q. And you see that on Exhibit 1340, the list
22 of signatures, you actually signed off on the
23 protocol as vice-president of medical affairs in
24 Ethicon; correct?

25 A. Correct.

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1 Q. Now, if you could, tell me in simple terms
2 the purpose of the protocol that we've marked as
3 Exhibit 1341. In just simple, general terms, what is
4 the purpose of this document?

5 A. So the -- a protocol within a clinical
6 research effort would be the document that describes
7 the -- the nature of the experiment, if you will,
8 that's to be undertaken and the methodology or the --
9 yeah, the methodology by which the experiment will be
10 run.

11 Q. When this document was written -- and it's
12 actually signed -- well, rephrase.

13 If you turn to the second page of it,
14 there's actually a signature by David Robinson, the
15 medical director?

16 A. Yes.

17 Q. What's the purpose of having David
18 Robinson sign this document?

19 A. As the medical director, he has -- he has
20 reviewed it and has agreed with its form.

21 Q. As a medical director, he has read this
22 document, presumably, every word, and he's confirming
23 with his signature that everything stated in this
24 document is accurate; correct?

25 A. Yes.

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1 Q. Let's turn, if we could --

2 MR. SNELL: Excuse me.

3 BY MR. SLATER:

4 Q. -- to Page 8. Actually, let me -- let me
5 take a step back. Let's turn to Page 7, if we could.

6 Page 7 provides a synopsis of the
7 protocol. That's what it's titled there; right?

8 A. Yes.

9 Q. Synopsis would just be a summary of some
10 key points?

11 A. Yes.

12 Q. And it points out at the top what the
13 objectives are and then it goes through the study
14 design and then the study population as you go down;
15 correct?

16 A. Yes. Uh-huh.

17 Q. The study population, it indicates, in
18 order for a woman to be included in this study, she
19 must have symptomatic pelvic organ prolapse of ICS,
20 which would be the International Continence Society,
21 POPQ Stage 3 or 4, suitable for surgical repair.

22 Do you see that?

23 A. I do.

24 Q. And when it says that a woman must meet
25 the following inclusion criteria, what's the

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1 significance of that in terms of a clinical study
2 like this?

3 A. It's -- the inclusion criteria and the
4 exclusion criteria would be the criterion -- the
5 criteria by which you define the study population,
6 who -- what is -- what is the population of patients
7 or subjects that you want to study.

8 Q. Why is an exclusion criteria established
9 for a study like this?

10 A. Well, to -- you want -- you're -- well,
11 there could be a lot of reasons, but you're trying to
12 homogenize the population so that the experiment
13 can -- you can reduce confounding variables. You're
14 trying -- you're trying to isolate so you can study
15 and test your hypothesis.

16 Exclusion could also be in place if you
17 think -- if you think there are subjects who should
18 not be included for medical reasons or -- I mean,
19 they're people who should be excluded because they
20 won't contribute to the experiment.

21 Q. And let's look to the next page. On Page
22 8 there's a heading that says, subjects who meet any
23 of the following criteria will be excluded from
24 participating in the study.

25 So these are categories of women that your

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1 company decided should not be studied; correct?

2 A. Should not be part of this study, yeah.

3 Q. Item Number 2 of the exclusion criteria
4 says, previous repair of pelvic organ prolapse
5 involving insertion of mesh.

6 Do you see that?

7 A. I do.

8 Q. So your company decided that if a woman
9 had previously had mesh inserted for a repair of some
10 form of pelvic organ prolapse, she should not be
11 included in this study; correct?

12 A. Correct.

13 Q. Let's go down further. Item -- let me --
14 let me start over.

15 Item Number 7 in the exclusion criteria
16 says, history of any pelvic radiation therapy.

17 Why was that an exclusion criteria?

18 A. Again, if you're -- if you're studying the
19 output of surgery or the -- the outcome of surgery,
20 in this particular case pelvic floor surgery, they
21 wanted to exclude any confounding influence that
22 radiation may have had on -- on the outcome.

23 Q. Was your company also aware that a woman
24 who had undergone pelvic radiation therapy may have
25 issues with being able to heal or whether or not

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1 she'd be compatible with having polypropylene
2 implanted in her body?

3 A. I don't think it has anything to do with
4 whether -- whether she had polypropylene put in her
5 body, but certainly radiation is a known risk factor
6 for adequacy of healing or robustness of healing.

7 Q. Let me ask you this: Did your company
8 ever study what would happen with a woman who had
9 pelvic mesh put in her body, any of your pelvic mesh
10 devices, and then later would develop cancer or a
11 similar disease and need to undergo either radiation
12 or chemotherapy or something like that?

13 A. Not --

14 Q. Did you ever -- did your company ever look
15 at that issue?

16 A. Not that I'm aware of.

17 Q. You would certainly agree with me that if
18 a woman has one of your pelvic mesh devices in her
19 body and then develops cancer and undergoes
20 radiation, chemotherapy, similar oncologic cancer
21 type treatments, that could have an impact on the --
22 the mesh within her body; correct?

23 MR. SNELL: Form.

24 BY MR. SLATER:

25 Q. Or her body's ability to tolerate the

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1 mesh.

2 MR. SNELL: Form and foundation.

3 THE WITNESS: No, I'm not aware of that
4 connection.

5 BY MR. SLATER:

6 Q. Did you ever look at that subject?

7 A. No.

8 Q. The Exclusion Criteria Number 10 says,
9 current evaluation or treatment for chronic pelvic
10 pain. For example -- example, interstitial cystitis,
11 endometriosis, coccydynia or vulvodynia.

12 That's one of the exclusion criteria for
13 this study; correct?

14 A. It is, uh-huh.

15 Q. And when it talks about current
16 evaluation, that would be if a woman is being
17 examined and they're considering maybe she has
18 interstitial cystitis, for example, she would meet
19 the exclusion criteria; right?

20 A. Yeah. So if she was being thought of as a
21 potential candidate for this study and her physician
22 said I believe she has one of these conditions, then
23 she would not be eligible.

24 Q. Well, if somebody is going to be evaluated
25 for one of these conditions, it doesn't necessarily

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1 mean it's been established they have it, it just
2 means that it's being entertained as a possible
3 diagnosis and an evaluation is ongoing.

4 A. Yeah. So -- so the evaluation would imply
5 that she does have pelvic pain. It may or may not
6 have been established what the reason for the pain
7 is.

8 Q. So if a doctor -- and I'm just taking the
9 first one in the list --

10 A. Uh-huh.

11 Q. -- entertains the possibility that a woman
12 had interstitial cystitis and part of his treatment
13 of her included some sort of an evaluation to
14 determine one way or the other, she would be excluded
15 from this study; correct?

16 A. I think if she had pelvic pain and
17 interstitial cystitis was being considered as part of
18 the differential diagnosis, she would have been --
19 she should have been excluded, yes.

20 Q. Okay. If you could, go to Page 14.

21 A. Okay.

22 Q. Page 14 of the Prolift+M clinical study
23 protocol is the introduction section; right?

24 A. Correct.

25 Q. What is the purpose of this section in

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1 this protocol?

2 A. I think all clinical protocols driven by
3 relevant standards call for an introduction section
4 just to -- to frame up the -- the clinical condition
5 for which the experiment is being undertaken.

6 Q. Would the purpose include setting the
7 context for why the study is being performed?

8 A. Sure. Yeah.

9 Q. If you could, turn to Page 15, the second
10 page of the introduction.

11 It says at the top, synthetic meshes,
12 first used for abdominal wall hernia repairs, are
13 often produced from materials originally used for
14 sutures.

15 And that's just a statement of fact that
16 originally sutures were used, then people began to
17 create meshes and began to use those meshes to treat
18 hernia. That's just a historical fact in terms of
19 the progression; right?

20 MR. SNELL: Form.

21 THE WITNESS: Can you just restate that?
22 Because I have one question about it.

23 MR. SLATER: Sure.

24 You know, it doesn't matter.

25 VIDEO OPERATOR: Doctor.

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1 BY MR. SLATER:

2 Q. Dr. Hart --

3 A. Yeah.

4 Q. -- you're covering your mic.

5 A. Oh, I'm sorry.

6 Q. Okay. The second sentence -- well,
7 rephrase.

8 The second sentence here on Page 15 points
9 out that synthetic meshes are able to provide support
10 where autologous tissues are not adequate.

11 Autologous tissues would be the woman's
12 own natural tissue; correct?

13 A. Correct.

14 Q. But they -- rephrase.

15 It's pointed out here that synthetic
16 meshes are able to provide support where autologous
17 tissues, which is the woman's own natural tissue, are
18 not adequate but they do add the risks of erosion and
19 rejection.

20 And that's just a statement of fact;
21 correct?

22 A. It is. I don't -- I don't agree with it,
23 but it is a statement of fact there.

24 So I -- I -- I would think rejection is
25 something different. Rejection to me is a

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1 immunologic reaction to a transplanted tissue.

2 That's -- to me, that's rejection. But certainly
3 erosion.

4 Q. Do you know why the term "rejection" was
5 used here?

6 A. No. It's -- I think -- my opinion, it's a
7 common mistake that's in the literature when they
8 call this rejection. I don't think it's really
9 rejection.

10 Q. When the literature or even your own
11 internal documents refer to rejection of the mesh,
12 what is it that they are saying? Because, obviously,
13 they're not talking about an immunologic rejection,
14 as you've described it --

15 A. Right.

16 Q. -- so what is the intended definition?

17 A. So I'm -- I'm -- I'm speculating because I
18 don't -- I didn't write this and I don't use that
19 word in this context, but I believe they -- they -- I
20 speculate that they could mean the body could have,
21 some people's reaction could be stronger than others'
22 in terms -- and foreign body reaction. I mean, I
23 speculate that could be what they're talking about.

24 Q. Are you referring to the fact there are
25 some women that just respond more negatively than

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1 other women? It's just known that there's high
2 responders, lower responders? Is that --

3 A. Yeah.

4 Q. Is that what you're talking about?

5 A. Yeah, there's -- that's true of sort of all
6 responses to body insult, if you will. And there's
7 variability in biologic response to anything,
8 including medicines and whatever. Yeah.

9 Q. This introduction at the top of Page 15
10 points out that synthetic meshes can provide support
11 where the woman's own natural tissue is not adequate
12 but the tradeoff is it adds the risks of erosion and
13 rejection.

14 That's what it says here; correct?

15 MR. SNELL: Form.

16 THE WITNESS: It does.

17 BY MR. SLATER:

18 Q. And that was --

19 MR. SLATER: I'm sorry. What's your
20 objection?

21 MR. SNELL: Form. Asked and answered.

22 He's already -- you've already -- this is the second
23 time you've covered that.

24 MR. SLATER: It's a different objection.
25 It's not form.

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1 MR. SNELL: No. No. No. Asked and
2 answered is a form objection.

3 MR. SLATER: Don't get excited. I don't
4 want you coughing.

5 MR. SNELL: I know.

6 MR. SLATER: Go ahead. Take a Luden's.
7 You'll be okay.

8 MR. SNELL: Go ahead.

9 MR. SLATER: Okay.

10 BY MR. SLATER:

11 Q. David Robinson, we already established,
12 signed off on this for medical affairs; correct?

13 A. That's correct, yeah.

14 Q. And you signed off as well; correct?

15 A. Uh-huh.

16 Q. Did you have an understanding of what the
17 word "rejection" was referring to, as used in this
18 document, when you signed off?

19 A. Yeah. I can't recall reading this -- this
20 word in this document that many years ago so --
21 however, when I read "rejection" in this context, I
22 have my own reaction to it. Every time is I don't
23 think that's the right word but...

24 Q. Let's go to the next page.

25 On the third page of the introduction,

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1 which is Page 16 of the protocol, there is discussion
2 of the transvaginal mesh procedure and the Prolift;
3 correct?

4 A. I'm sorry. Where?

5 Q. Right at the top of the page under the
6 table it says --

7 A. Under the table.

8 Q. -- the longest-term followup data is with
9 the precursor to the Prolift system, known as
10 transvaginal mesh.

11 See that?

12 A. Yes, I do.

13 Q. So there's a discussion about essentially
14 the -- well, rephrase.

15 So this now discusses on Page 16 the TVM
16 procedure and then talks about the Prolift; correct?

17 A. It does, yeah.

18 Q. And the reason to discuss the Prolift is
19 obviously because the Prolift+M is essentially the
20 same thing, just you're changing the mesh material.

21 A. Yes.

22 Q. Okay. And in this document, which was
23 signed by David Robinson, the Prolift is discussed in
24 this paragraph on Page 16, the second paragraph.

25 Do you see that?

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1 A. Uh-huh.

2 Q. And what it says is, although the Prolift
3 significantly reduces recurrences compared to
4 traditional POP repairs -- and I want to stop there.

5 He's making that statement based on,
6 presumably, data that he had available to him?

7 A. Yes.

8 Q. Do you know what data he was relying on to
9 say that?

10 A. No.

11 Q. It's pointed out here that the Prolift
12 significantly reduces recurrences compared to
13 traditional repairs. Well, rephrase.

14 It's pointed out here that the Prolift can
15 lead to complications such as mesh exposure and mesh
16 retraction.

17 Do you see that?

18 A. I do.

19 Q. And the document goes on, mesh exposure is
20 a common complication. And I want to stop there.

21 In this document, which David Robinson
22 signed off on, he characterizes mesh exposure as a
23 common complication; correct?

24 A. He did.

25 Q. And this is a document you also signed off

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1 on; correct?

2 A. Uh-huh.

3 Q. You just have to say yes just --

4 A. Yes. Yes.

5 Q. -- for our formality. Thank you.

6 If you go to the next sentence, it says,
7 mesh retraction, shrinkage, is less common but is
8 considered more serious.

9 So it's saying mesh retraction happens
10 less commonly than mesh exposure?

11 A. It does.

12 Q. It --

13 A. Yes.

14 Q. The protocol points out that mesh
15 retraction can cause vaginal anatomic distortion,
16 which may eventually have a negative impact on sexual
17 function.

18 That's one of the potential consequences
19 of mesh retraction with a Prolift; correct?

20 A. Yes.

21 Q. Further discussing the Prolift's
22 complications, this says, its treatment is -- well,
23 rephrase.

24 And then it's pointed out, its treatment
25 is difficult, again talking about mesh retraction.

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1 Treating that is difficult; correct? That's what it
2 says here.

3 A. Well, I -- I presume they're referring to
4 the -- the sentence exactly preceding, eventually
5 have negative impact on sexual function. Its
6 treatment is difficult. Yeah.

7 Q. This indicates further, the next
8 sentence -- rephrase.

9 In discussing the Prolift complications
10 this next says, additionally, the scar plate that
11 forms with ingrowth of tissue into the mesh can cause
12 stiffness of the vagina that further impacts sexual
13 function in a negative manner.

14 And that's a statement of a complication
15 that can occur with a Prolift; correct?

16 A. Correct.

17 Q. Finally, at the end of this sentence it's
18 pointed out, in an effort to minimize these
19 complications, a lighter-weight alternative mesh for
20 Prolift has been introduced.

21 And that's a statement of what your
22 company hoped would be the result of the use of the
23 Prolift+M, that these complications described here
24 could be reduced; correct?

25 A. It was a hypothesis.

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1 Q. It had not been proven; correct?

2 A. Correct.

3 Q. And even when the Prolift+M went on the
4 market, it still had not been proven; correct?

5 A. Correct.

6 Q. And, in fact, over the entire course of
7 time the Prolift+M was on the market it turned out it
8 did not reduce those complications; correct?

9 A. I believe that to be true. I don't have
10 the data, you know, solid in my head.

11 Q. But from everything you can think of
12 now --

13 A. I -- yeah, I don't --

14 Q. -- that's a true statement; right?

15 A. I can't -- I don't have evidence in my head
16 that says that's not a true statement. Yeah.

17 Q. Okay. Go to the next page, if you could,
18 Page 17.

19 On Page 17 at the top there's a discussion
20 about Ultrapro, which is the trade name of the
21 partially absorbable material that your company began
22 to use with the Prolift and called it the Prolift+M;
23 right?

24 A. Right.

25 Q. In the second sentence it talks about the

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1 history of the use of Ultrapro. Well, rephrase.

2 This section talks about the fact that
3 Ultrapro was currently indicated to treat hernias,
4 stabilization of the abdominal wall; correct?

5 MR. SNELL: Where are you at? I'm sorry.

6 MR. SLATER: Very top of the page.

7 MR. SNELL: Oh, you're on 17. I'm sorry.

8 THE WITNESS: Yeah.

9 MR. SNELL: I was on the wrong page.

10 THE WITNESS: Yes.

11 MR. SNELL: Go ahead.

12 MR. SLATER: I'll just ask it again just
13 because I don't want to make Burt a star.

14 MR. SNELL: No. That's my bad. Sorry.

15 MR. SLATER: That's okay. No big deal.

16 MR. SNELL: I was on the wrong page.

17 MR. SLATER: That's fine.

18 BY MR. SLATER:

19 Q. At the very top of Page 17, in discussing
20 the history with Ultrapro it points out, first of
21 all, that its current indication was to treat
22 hernias; right? That's essentially what that first
23 sentence is saying; right?

24 A. Yes.

25 Q. Then it says, however, some gynecologists

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1 have used it for prolapse repair, though the
2 information gathered from these cases is limited due
3 to the small number of cases, the mesh was placed
4 from an abdominal rather than vaginal approach, the
5 size of mesh used was small relative to the current
6 intended use.

7 And that's just your company's overview of
8 what information you had from whatever doctors were
9 trying to use Ultrapro to treat prolapse up until
10 this point; fair?

11 A. Fair.

12 Q. And then if you go to the next sentence,
13 next section, it says, the rationale for the clinical
14 evaluation. And that's essentially what, when we say
15 the rationale?

16 A. So why is it that we want to undertake this
17 experiment.

18 Q. And at the very bottom of that paragraph
19 it says, the purpose of this clinical study is to
20 evaluate the clinical performance of the Prolift
21 system with the new, lighter-weight mesh.

22 And that, in a nutshell, is the reason why
23 the Prolift+M clinical study was performed; correct?

24 A. Yes.

25 Q. If you could, let's go to Page 30.

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1 Actually, Page 31. Okay.

2 Looking at Page 31, there's a Section 10.6
3 that says, anticipated adverse device effects.

4 What does that mean?

5 A. So as part of a clinical protocol you would
6 want to define up front what adverse events might you
7 expect, based on your current knowledge of this --
8 this procedure or these materials and so forth, so
9 there -- there would be a set of potential
10 complications or adverse effects that are related to
11 device use that you might anticipate going into the
12 trial.

13 Q. And in this case, as you look through
14 this, this is actually a bullet-pointed description
15 of what we had read before as the adverse events that
16 were known to occur with the Prolift, basically;
17 correct?

18 MR. SNELL: Form.

19 THE WITNESS: Oh, and any other surgery
20 in -- in that area for this condition, but yes.

21 BY MR. SLATER:

22 Q. Well, if you were to compare what's on
23 Page 31, those bullet points --

24 A. Uh-huh.

25 Q. -- to the paragraph on Page 16 in the

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1 introduction that discussed the complications known
2 with the Prolift, it's the same information.

3 A. Yes.

4 Q. Okay. So --

5 A. Well, hang on one second. Sorry.

6 So the last bullet on Page 31 is not
7 included in 16. I think the punctured lacerations,
8 vessels, nerves, et cetera, I don't think is on Page
9 16.

10 Q. As we look at 10.6, the anticipated
11 adverse device effects, these anticipated
12 complications are complications that were known to
13 occur with the Prolift and that's why it was
14 anticipated they would occur to some of the patients
15 with the Prolift+M; correct?

16 A. Correct.

17 Q. And if we go through this table, the first
18 one is, mesh exposure is a common complication, which
19 can be managed by excision and closure.

20 Do you see that?

21 A. Uh-huh. Yes.

22 Q. The second one, mesh retraction or
23 shrinkage is less common but is considered more
24 serious than mesh exposure. It can cause vaginal
25 anatomic distortion, which may eventually have a

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1 negative impact on sexual function. Shrinkage of the
2 mesh is expected under normal circumstances; however,
3 excessive shrinkage resulting in pain is not a common
4 finding.

5 That's the second adverse event that was
6 anticipated.

7 A. Yes.

8 Q. The third one, the scar plate that forms
9 with ingrowth of tissue into the mesh can cause
10 stiffness in the vagina that further impacts sexual
11 function in a negative manner.

12 That's another adverse event that was
13 anticipated with the Prolift+M; correct?

14 A. Correct.

15 Q. And the last one, punctures or lacerations
16 of vessels, nerves, bladder, urethra or bowel may
17 occur during Gynecare Prolift guide passage and may
18 require surgical repair.

19 That's the last one listed; correct?

20 A. It is.

21 Q. Now, I want to ask you a question about
22 the mesh retraction that was anticipated.

23 MR. SLATER: Do you want to just tell me
24 something?

25 We'll do it the break.

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1 BY MR. SLATER:

2 Q. I want to ask you about the mesh
3 retraction here. It talks about shrinkage and says,
4 shrinkage of the mesh is expected under normal
5 circumstances.

6 And that's just a statement that with any
7 polypropylene mesh there's going to be some shrinkage
8 by nature of the fact that there's going to be some
9 fibrotic formation around it and it's going to cause
10 a shrinkage of the mesh when the scar tissue grows
11 into and around the mesh. That's -- that happens, to
12 some extent, in any person at any time; correct?

13 MR. SNELL: Form.

14 Go ahead.

15 THE WITNESS: So, as I said, I think,
16 whenever it was, a few months ago, I don't -- I don't
17 think the mesh shrinks. I think there's scar around
18 it and it does contract, and it retracts to a
19 variable extent in different people but it -- it's --
20 yes.

21 MR. SLATER: Let me ask it again. I
22 actually was trying to say that but probably not
23 clear enough for you, which -- which I can
24 understand. So let me try to say that again.

25 BY MR. SLATER:

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1 Q. Here in the second bullet point it says,
2 shrinkage of the mesh is expected under normal
3 circumstances.

4 Is that just a recognition that in any
5 woman who has polypropylene pelvic mesh from your
6 company in her body, when the scar tissue forms
7 around it, to some extent, the scar tissue is going
8 to push down and grow into the mesh and cause the
9 mesh to, we call it mesh contraction, but just
10 squeeze it down somewhat?

11 A. Yeah, it's scar contraction, and so the
12 area covered by mesh does get smaller.

13 Q. And that's something that your company
14 looks at, as described here, as something that
15 occurs, it's going to occur to everybody, and anybody
16 would know that.

17 A. So it's -- I -- I don't know about
18 everybody, but it's a very common --

19 Q. Let me rephrase it.

20 A. Yeah.

21 Q. Let me rephrase it.

22 So that part of this sentence is saying
23 this, quote, unquote, shrinkage, which we've defined,
24 is -- is going to happen and under normal
25 circumstances it's probably not something to be that

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1 concerned about; is that --

2 A. Correct.

3 MR. SNELL: Form.

4 MR. SLATER: Okay.

5 BY MR. SLATER:

6 Q. Then it says, however, excessive shrinkage
7 resulting in pain is not a common finding.

8 So that's basically saying, in some women
9 there's going to be more shrinkage and it's going to
10 lead to pain and that's not the normal. That's not
11 what's expected in all women.

12 A. Correct. It's less common.

13 Q. Okay. And that's the -- that's the
14 severe -- rephrase.

15 That's the -- the shrinkage that is of
16 concern because once a woman has pain from the
17 shrinkage or the retraction, then you have a very
18 serious problem because treatment can be very
19 difficult --

20 A. Yeah.

21 Q. -- in some circumstances.

22 A. I'm not an expert in this space.

23 MR. SNELL: Object to form.

24 THE WITNESS: My understanding is it's --
25 it can be more difficult to treat.

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1 MR. SLATER: Okay.

2 Let's take a break.

3 VIDEO OPERATOR: Time is now 10:37.

4 This is the end of Disk Number 1. We're
5 going off the record.

6 (Recess, 10:37-10:45 a.m.)

7 (Exhibits T-1342A and T-1343A were marked
8 for identification.)

9 VIDEO OPERATOR: The time is now 10:45.

10 This is the beginning of Disk Number 2.
11 We are back on the record.

12 BY MR. SLATER:

13 Q. What we just went through was the final
14 version of the protocol, March 22, 2010, and it
15 actually says that it's Protocol Amendment 4, and
16 that's been identified to us as the final, final
17 version of the -- of the protocol.

18 Now what I'm showing you is 1342 and
19 1343, which is the --

20 A. Can I -- can I just --

21 Q. Sure.

22 A. So I don't know that this -- so this says
23 Final Version Number 1, this says Final Version
24 Number 5. I don't know myself that this is final
25 version, final, final, final version. I don't know

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1 that.

2 Q. Okay. We were told that -- is that
3 Exhibit 1340 --

4 A. 1.

5 Q. -- Exhibit 1341, that that's the
6 signatures for and the actual final version of the
7 final version.

8 A. Okay.

9 Q. Because I guess the final version got
10 amended multiple times --

11 A. At least it must have.

12 Q. -- to end up in March of 2010.

13 A. Yeah.

14 Q. That's what we were told --

15 A. Okay.

16 Q. -- that this is the last version of it.
17 Best I can tell you.

18 A. Okay.

19 Q. And what I've been told is that Exhibit
20 1342 and '43 is the first iteration --

21 A. Uh-huh.

22 Q. -- of the final version --

23 A. Uh-huh.

24 Q. -- of the protocol for the Prolift+M
25 study.

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1 And you see that you actually --

2 A. Yeah, this is same study.

3 Q. -- signed that.

4 A. I did. Uh-huh. I see that.

5 Q. And I can tell you we also -- I didn't
6 bring them, but there are draft versions before the
7 August 10, 2007, Final -- Final Version 1.

8 A. I'm sure, yeah. That's normal routine.

9 Q. Now, all I want to confirm is that --

10 A. I guess I need to be able to compare.

11 Q. It's basically a comparison of a couple
12 pages.

13 If you look at the -- the final version of
14 the protocol, I'm going to call that --

15 A. '43.

16 Q. -- March 2010 version --

17 A. Yes.

18 Q. -- the final version of the protocol, on
19 Page 15 there's a paragraph that describes Prolift
20 complications and --

21 A. Uh-huh.

22 Q. -- the effort to minimize those
23 complications with the Prolift+M.

24 A. That would be on Page 16.

25 Q. Exactly.

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1 And I just want to match them up to show
2 that in August of 2007 the same language was in this
3 protocol.

4 MR. SNELL: Excuse me.

5 THE WITNESS: That's not 16.

6 MR. SLATER: It is. Page 16 in March of
7 2010, Page 15 in August of 2007.

8 THE WITNESS: I'm not getting the right
9 one on this. This is 2007.

10 MR. SLATER: Yeah.

11 BY MR. SLATER:

12 Q. If you go to Page --

13 A. And you say which page?

14 Q. Page 15.

15 A. 15. Okay. I got that.

16 Q. And it's the second paragraph.

17 A. Got it.

18 Q. And if you go to the other one, Page 16.

19 A. Okay. I had them backwards.

20 Q. Okay. So I'll start over.

21 A. Yeah. I've got it.

22 Q. If you compare the March 2010 final, final
23 version of the Prolift+M protocol and you compare
24 that to the first version of the final protocol from
25 August of 2007, almost three years earlier, if you

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1 match up the paragraphs about the Prolift and its
2 complications in the introduction sections, they're
3 the same; correct?

4 A. Yes.

5 Q. Okay. Now, in the August 2007, if you'd
6 turn to Page 28 --

7 A. Got it.

8 Q. -- and you compare that to Page 31 of the
9 March 2010 version, what I want to do is compare this
10 and I want to ask you a question because there are a
11 little bit of a difference.

12 If you look at the August 2007 version of
13 the final protocol for the Prolift+M study and you
14 look at Section 10.6, these are the anticipated
15 adverse device effects, it lists what were
16 anticipated.

17 Do you see that?

18 A. I do.

19 Q. And if you compare that to what was in the
20 final version of this document signed in March of
21 2010, I want to go through it and then point out to
22 you something that's different and ask you a question
23 about that. Okay?

24 A. Okay.

25 Q. The first bullet point in each is the

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1 same.

2 A. Uh-huh.

3 Q. Correct?

4 Talking about mesh exposure.

5 A. Yes.

6 Q. The second one, mesh retraction, the first
7 sentence is the same in both; right?

8 A. Yes.

9 Q. The second sentence is the same; correct?

10 A. Yes.

11 Q. Talking about vaginal anatomic distortion?

12 A. Yes.

13 Q. The March 2010 version adds a sentence.

14 It adds that, shrinkage of the mesh is expected under
15 normal circumstances; however, excessive shrinkage
16 resulting in pain is not a common finding.

17 Do you see that?

18 A. I do.

19 Q. And do you know why that language was
20 added?

21 A. I don't.

22 Q. Okay. The third bullet point is the same
23 between the two; correct?

24 A. Yes.

25 Q. And the fourth bullet point is the same;

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1 correct?

2 A. Yes.

3 Q. Okay. You could put that aside.

4 Well, let me ask you one question,

5 actually. I'm sorry. I said put it aside, but I

6 don't know if you'll need it.

7 The August 2007 version of the final

8 protocol for the Prolift+M study was also signed --

9 was signed by -- rephrase.

10 The August 2007 version of the final

11 protocol for the Prolift+M study was signed on August

12 14, 2007, by David Robinson; correct?

13 A. Correct.

14 Q. And David Robinson also signed the March

15 2010 version, which we've been told is the final,

16 final iteration. And he signed that as well;

17 correct?

18 A. Correct.

19 Q. So, presumably, with regard to that one

20 additional sentence added to the protocol about mesh

21 retraction, David Robinson, whether he made the

22 decision, he certainly signed off on adding that

23 additional language; correct?

24 A. Correct.

25 Q. Okay. Okay.

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1 MR. SLATER: I don't know, Burt. You're
2 dealing out those Luden's.

3 MR. SNELL: They come from Mary Ellen
4 so --

5 MR. SLATER: Mary Ellen is the -- she's
6 the top source for the Luden's around here?

7 MR. SNELL: Yeah.

8 MR. SHERIDAN: She's the Luden
9 intermediary.

10 MR. SNELL: Yes.

11 Thanks.

12 (Exhibit T-1344A was marked for
13 identification.)

14 MR. SNELL: Wait. I think that one is
15 mine.

16 That's 1344?

17 MR. SLATER: 1344.

18 BY MR. SLATER:

19 Q. Dr. Hart, what I've provided you is
20 Exhibit 1344, which is, according to what the
21 attorneys for Johnson & Johnson have told us, is the
22 current version of the TVT IFU that has been in use
23 since November 29, 2010. Just so you know what we've
24 been told this document is, that's what has been
25 represented to us.

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1 A. Okay.

2 Q. And what I want to ask you about is on the
3 second page, there's a -- a description of the
4 Gynecare TVT device and in the second paragraph it
5 talks about the fact that it's -- in the second
6 paragraph under the Gynecare TVT device -- rephrase.

7 In the second paragraph under Gynecare TVT
8 device it says, Prolene mesh is constructed of
9 knitted filaments of extruded polypropylene strands
10 identical in composition to that used in Prolene
11 polypropylene non-absorbable surgical sutures. I
12 want to ask you a couple of questions about that
13 sentence and then go through this paragraph a little
14 with you.

15 First of all, Prolene mesh is the material
16 for the TVT mesh; correct?

17 A. Correct.

18 Q. And what this is pointing out is that the
19 strands that make up the mesh are exactly the same as
20 what you would find in a Prolene suture. It's the
21 same material; correct?

22 A. That's what it says, yes.

23 Q. And, in fact, what ultimately happens is
24 you're essentially taking Prolene sutures and they
25 get woven together through a process that probably

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1 neither of us understands that well, or certainly I
2 don't, and -- and they take a lot of sutures and they
3 build the mesh with that through a knitting process.

4 Let me ask the question differently
5 because I threw in the thing about not understanding,
6 and that's sloppy lawyering.

7 If I'm -- if I'm correct -- and tell me if
8 I'm wrong -- essentially, what happens is there's a
9 process whereby Prolene sutures are taken and they're
10 knitted together through some process and ultimately
11 they're combined and knitted together and it creates
12 the mesh.

13 A. I don't -- I don't know that it's actually
14 suture that is used to -- to -- I don't think -- I
15 don't know that the strands are extruded exactly in
16 the same run, in the same machine. It's the same
17 material and the strands would be extruded in a
18 similar -- with the similar or the same process, but
19 I don't think you can say you take a suture and then
20 turn it into a mesh.

21 Q. Okay. Let me ask it differently, then.

22 It indicates that the mesh is constructed
23 of knitted filaments of extruded polypropylene
24 strands that are identical in composition to what is
25 used in Prolene sutures, so it's the same material

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1 but what is knitted into the mesh are strands that
2 are knitted together and that creates the mesh.

3 A. True.

4 Q. Okay. It points out that the mesh is
5 approximately .027 inches thick. So now we know how
6 thick it is.

7 That's what that tells us; right?

8 A. Uh-huh.

9 Q. This then indicates, this material when
10 used as a suture has been reported to be non-reactive
11 and to retain its strength indefinitely in clinical
12 use.

13 Do you see that?

14 A. I do.

15 Q. Now, that would be information that
16 medical affairs would have confirmed was accurate;
17 right?

18 A. As part of a team approving the IFU, yes.

19 Q. But certainly medical affairs would have
20 had to sign off and say yes, that is a true statement
21 that can be relied on by physicians; right?

22 A. Right.

23 Q. And I want to ask you a few questions
24 about that and talk to you specifically about Prolene
25 suture.

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1 Prolene suture is something that's been in
2 use for a long time for various surgeries within the
3 body; correct?

4 A. Correct.

5 Q. In fact, Prolene suture is something you
6 used when you were performing surgery in the chest.

7 A. For decades.

8 Q. For decades.

9 In terms of the literature that exists
10 with regard to Prolene sutures, does the literature
11 describe any serious risks from the use of a Prolene
12 suture?

13 A. I can't say that I have direct knowledge of
14 the entire body of literature of the use of
15 polypropylene sutures, so I would be relying on my --
16 my personal experience of 30-some years, I guess.

17 Q. Well, let me ask it this way: You worked
18 as a -- as a heart surgeon for a long time; right?

19 A. I did.

20 Q. You worked with Prolene suture on a daily
21 basis, pretty much; right?

22 A. Uh-huh.

23 Q. You certainly were familiar with the
24 medical literature with regard to sutures. It's
25 something that you would have been aware of.

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1 A. No. No, I wouldn't have reviewed
2 literature around sutures.

3 Q. Well, let me ask you this: In your
4 position as -- well, rephrase.

5 From your perspective, based on all of the
6 information that's available to you, and that
7 includes, obviously, for any medical affairs
8 director, their -- their own personal experience --

9 A. Right.

10 Q. -- and background plus what they've
11 learned and seen while working for Johnson & Johnson
12 or Ethicon --

13 A. Uh-huh.

14 Q. -- are you aware of serious adverse events
15 connected to the use of Prolene suture in the body?

16 A. Yes.

17 Q. What?

18 A. We have had -- we have had over the years
19 complaints of either breakage or knot slippage.
20 Those -- those are the ones that come to mind
21 immediately.

22 Q. When you say "breakage," what does that
23 mean?

24 A. The suture fragments, breaks.

25 Q. What is knot slippage?

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1 A. A -- a surgeon would tie a knot to hold two
2 strands of suture together and -- and the knot comes
3 unraveled and untied.

4 Q. What you need is a Navy guy to tie the
5 knot because they tie really good knots.

6 A. Probably true.

7 Q. Salute to your counsel.

8 In terms of the biocompatibility of
9 Prolene suture, are there serious adverse events that
10 you're aware of with regard to the use of Prolene
11 suture in the human body?

12 A. No.

13 Q. If one takes the -- well, let me ask you
14 this: I've seen reference in some places to a suture
15 erosion, that that's something that can occur, a
16 suture can erode.

17 Is that considered a serious problem or is
18 that something that's considered to be easily
19 treated?

20 A. I think it would depend on what the suture
21 was and what it eroded into, I guess.

22 I mean, again, having used it for decades,
23 I can't think of a single case where I actually had a
24 patient who had a problem because one of my
25 polypropylene sutures eroded into something.

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1 Q. Okay. From your -- well, rephrase.

2 To the extent of your knowledge and your
3 experience and what you know as you sit here now,
4 you're not familiar with a suture erosion causing --
5 causing a serious problem for a patient.

6 MR. SNELL: Form.

7 BY MR. SLATER:

8 Q. And I'm not just talking about your own
9 personal experience but just what you've seen --

10 A. Yeah.

11 Q. -- working as a medical affairs
12 director --

13 A. Yeah.

14 Q. -- vice-president and chief medical
15 officer.

16 A. I can't -- I can't recall during my time at
17 Ethicon having been involved with an analysis or
18 becoming aware of a complaint through our normal
19 complaint system regarding a suture erosion causing
20 an adverse event. I don't see all of those.

21 Q. Certainly nothing you've ever been made
22 aware of?

23 A. Not that I can recall, no.

24 Q. It's my understanding that a suture will,
25 just like any foreign body, will create some sort of

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1 a foreign body reaction and some fibrotic tissue will
2 grow along the suture.

3 That's normal and expected; right?

4 A. Yes.

5 Q. To your knowledge, is there any serious
6 adverse event associated with that?

7 A. Again, in my personal experience of
8 however -- I don't know how many thousands and
9 thousands of patients I took care of with Prolene
10 sutures and -- and re-operated on many of them, or
11 not my patients, probably somebody else's, but
12 re-operations where Prolene sutures had been used
13 prior, I certainly -- I certainly encountered the
14 mild, I saw the mild fibrotic reaction that could
15 occur around a Prolene suture but I can't remember a
16 single case as I sit here that say, oh, this patient
17 had a problem because there was this reaction around
18 this suture.

19 Q. In all the time you've been with Ethicon
20 and Johnson & Johnson has any issue ever been brought
21 to your attention where the -- where some fibrosis on
22 a suture led to any problem for a patient anywhere in
23 the body, including the pelvis, the vagina, anything?

24 A. Polypropylene suture?

25 Q. Yeah.

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1 A. Not that I can recall.

2 Q. Okay. And tell me if I'm wrong or if I'm
3 right: Your company in evaluating the mesh that your
4 company has used in its pelvic mesh devices has
5 relied, to some extent, on the history of the use of
6 sutures within the human body as a predictor or as
7 some evidence of whether or not it would be safe.

8 A. Polypropylene, yes.

9 Q. Okay. Now, would you agree with me that
10 the profile of risks with Prolene suture,
11 polypropylene, which is made of polypropylene, is
12 different from the profile of risks with the
13 polypropylene meshes that your company sells for
14 implantation into the female pelvis?

15 MR. SNELL: Form.

16 THE WITNESS: Can I ask a --

17 BY MR. SLATER:

18 Q. Do you understand what I'm getting at?

19 A. I can ask you a clarifying question?

20 Q. Sure.

21 A. Are you talking about are there different
22 risks associated with the mesh than there are with a
23 suture when the -- when mesh is used?

24 Q. Let me ask you this: If you compare the
25 risks as between Prolene suture as compared to the

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1 risks with your pelvic mesh devices, is there a
2 difference in the risks and the severity and the
3 treatability of the risks? In terms of the risk
4 profiles, are there different?

5 MR. SNELL: Can you read that back,
6 actually? Thank you.

7 (The court reporter read the requested
8 portion of the record.)

9 MR. SNELL: Form objection.

10 THE WITNESS: Well, I think if you -- if
11 you're not implanting mesh, you can't have mesh
12 exposure, I think, so that's different.

13 BY MR. SLATER:

14 Q. Anything else?

15 A. Yeah. I think -- I think if we're talking
16 about mesh contracture but not shrinkage, which I
17 don't ascribe to, I don't -- I don't have direct
18 knowledge that we would talk about scar contracture
19 causing a problem with an individual suture in place
20 as compared to a mesh.

21 Q. Tell me if I understand this: In terms of
22 your company's representations regarding the safety
23 and effectiveness of the TVT and the other pelvic
24 mesh devices, one of the things that's relied on is
25 the history of clinical use of polypropylene sutures

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1 in the human body.

2 That's one of the things that's relied on;
3 correct?

4 A. Yes.

5 Q. And that's -- rephrase.

6 And the history of the clinical use of
7 sutures is also something that's relied on, in part,
8 with regard to Prolene Soft mesh, which is what was
9 used in the Prolift and also for Ultrapro; correct?

10 A. Yes.

11 Q. Okay. To your knowledge, does the
12 literature contain reports of serious -- rephrase.

13 To your knowledge, does the medical
14 literature contain reports of severe, life-altering
15 complications being suffered by women as a result of
16 sutures, polypropylene suture, in the body?

17 A. I suspect it does with regard to suture
18 breakage. I don't -- I don't have direct knowledge
19 of what that looks like, but there's got to be a case
20 report somewhere that talks about a polypropylene
21 suture fracturing and causing a severe adverse event.

22 Q. Are you thinking about that in the context
23 of a cardiac-type procedure or --

24 A. Or anyplace else it was used, but yeah. So
25 if you lose mechanical integrity.

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1 Q. Is there any specific instance you can
2 think of now where there's a report of a loss of
3 mechanical integrity where a suture broke and that
4 led to a serious, a severe, life-altering
5 complication?

6 A. I can't cite it but I'm sure -- I know it's
7 there.

8 Q. Is there an example you can give me where
9 you know that that's happened at some point?

10 A. Sure. In my own lifetime I had -- I had a
11 suture or two break that caused a -- early that
12 caused a disruption to a vascular anastomosis, and
13 we -- and so we do get complaints regarding that from
14 time to time in our -- in our normal, everyday
15 post-market surveillance.

16 Q. Are you familiar with anything in the
17 literature pointing to a polypropylene suture leading
18 to a chronic, untreatable pain condition? Is that
19 something you're aware of ever being reported?

20 A. Not -- no, not -- not as a direct reaction
21 to the suture. But if the suture failed, it could
22 cause a problem and that problem could lead to
23 chronic pain, I presume.

24 Q. But you only can tell me that in a general
25 sense, not with specificity, like a specific

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1 situation?

2 A. Say that again.

3 Q. I'll rephrase.

4 When you say that, you're saying just in a
5 general sense, you can imagine that could occur but
6 there's not a specific example you could point to me
7 right now?

8 A. Correct.

9 MR. SLATER: Oh, you switched during the
10 break? Okay. Great.

11 BY MR. SLATER:

12 Q. This paragraph in the TVT IFU about the
13 Prolene mesh says, this material when used as a
14 suture has been reported to be non-reactive.

15 What does that mean, to be non-reactive?

16 A. I think -- I think it implies that when
17 implanted in the body as a suture, the polypropylene
18 has a limited and probably insignificant tissue
19 reaction.

20 Q. When you talk about the tissue reaction,
21 would that be, in other words, a limited,
22 insignificant foreign body reaction?

23 A. Uh-huh. Yes.

24 Q. Okay.

25 (Exhibit T-1345A was marked for

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1 identification.)

2 MR. SNELL: Thank you.

3 BY MR. SLATER:

4 Q. What I've handed you as Exhibit 1345 is a
5 document that comes from the design history file for
6 Gynemesh Prolene Soft mesh, just so you know its
7 origin. And I can actually give you, might as well
8 mark it. There's no downside to marking this, in
9 fairness.

10 (Exhibit T-1346A was marked for
11 identification.)

12 BY MR. SLATER:

13 Q. I've marked as Exhibit 1346 what was
14 provided to me as identifying where it came from.
15 It's attached to that.

16 MR. SHERIDAN: Yeah, I have it.

17 BY MR. SLATER:

18 Q. 1345 is a December 2, 1999,
19 biocompatibility risk assessment for soft Prolene
20 mesh, which, according to Exhibit 1346, came from the
21 design history file.

22 Do you see that?

23 A. I do.

24 Q. And you understand that one of the
25 standard things to do as part of a design history

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1 file is to document a biocompatibility risk
2 assessment for a mesh device?

3 A. Yes.

4 Q. Okay. This -- well, let me ask you this:
5 What is the purpose -- rephrase.

6 What is the purpose of the
7 biocompatibility risk assessment in this context?

8 A. Well --

9 Q. Why is that done?

10 MR. SNELL: Just give him a chance to read
11 it.

12 Have you ever seen this?

13 THE WITNESS: Yeah.

14 BY MR. SLATER:

15 Q. I'm asking -- I'm asking, in a general
16 sense, why is a biocompatibility risk assessment
17 performed?

18 A. Yeah. So not a design history expert nor
19 am I a toxicologist, obviously, but my understanding
20 would be that during -- during development one needs
21 to consider if you're going to have an implant what
22 the potential impact and reaction within the body
23 might be. High level, very generally.

24 Q. Okay. The first paragraph of this risk
25 assessment says, the raw material used for the

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1 manufacture of soft Prolene mesh will be the same
2 material used for current Prolene polypropylene mesh
3 as well as natural, uncolored polypropylene suture.

4 So that's telling us at the very basic
5 level the same material as in polypropylene sutures,
6 Prolene mesh and Prolene Soft mesh; correct?

7 A. Yes.

8 Q. It then -- rephrase.

9 This then points out that in the Prolene
10 Soft mesh the filaments that are used to weave the
11 mesh have a smaller diameter than what is in Prolene
12 mesh.

13 That's what it says in the next sentence,
14 basically; correct?

15 A. Let me read, please. Okay?

16 Q. Sure.

17 A. Yes.

18 Q. In the second paragraph, the very bottom
19 of that paragraph, it says, however, there is an
20 extensive history of safe clinical use with
21 polypropylene, specifically Prolene mesh and
22 natural -- natural and blue Prolene suture, that
23 demonstrates that this material is one of the most
24 inert biomaterials available for implantation.

25 Do you see that?

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1 A. I do.

2 Q. When your company refers to an extensive
3 history of safe clinical use with polypropylene, that
4 would be a reflection of somebody's judgment that in
5 looking at the data available about how this material
6 is actually reacted in the human body, it's being
7 described as safe here.

8 A. I'm going to read the whole paragraph. So
9 one sec.

10 Okay. I'm sorry. Can you ask it again?
11 I've read it.

12 Q. Yeah. I'm going to -- I'm going to ask a
13 different question.

14 In -- in essence, a comparison is being
15 made here, and -- and what we're hearing is that
16 because there's some judgment by somebody named Tom
17 Barbolt, who wrote this document, that there's an
18 extensive history of safe clinical use with Prolene
19 mesh and Prolene suture, this material, the
20 polypropylene, is one of the most inert materials
21 available.

22 So he's basically saying I'm drawing on
23 what we know from the clinical history to make this
24 statement.

25 A. As a starting point, yeah.

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1 Q. Okay. You would agree with me that in
2 evaluating Prolene mesh you would want to evaluate
3 ultimately -- well, rephrase.

4 You would agree with me that if you're
5 going to do a -- an evaluation of the
6 biocompatibility of a specific mesh material, in this
7 case Prolene Soft mesh, you would ultimately want to
8 do the full evaluation on that material in order to
9 do a full biocompatibility assessment, from a medical
10 affairs perspective; correct?

11 MR. SNELL: Form.

12 THE WITNESS: From -- so, again, from a
13 medical affairs perspective, not being a
14 toxicologist, I -- I would expect the toxicology
15 folks who are making the biocompatibility evaluation
16 and recommendation to draw on what they already know
17 and then, according to best toxicology ISO standards
18 and so forth, do the testing that's required.

19 MR. SLATER: Okay.

20 BY MR. SLATER:

21 Q. And if we look just above, and I think you
22 probably just read that language before we -- before
23 you answered that, there's an ISO standard --

24 That would be the International Standards
25 Organization?

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1 A. Correct.

2 Q. -- and the guideline that says that
3 pursuant to that standard, a number of
4 biocompatibility tests need to be addressed, and
5 they're listed there; right?

6 A. Yes.

7 Q. And one of them is cytotoxicity. That's
8 the first one listed; right?

9 A. Yes.

10 Q. Do you know what cytotoxicity is?

11 A. Again, high level. Cytotoxicity would be
12 whether or not a particular material would be, have
13 adverse impact on cells. Cyto- means cells.

14 Q. It's my understanding that cytotoxicity
15 testing in the context of biocompatibility is to
16 determine whether or not contact between the material
17 and tissue causes damage or destruction of the cells
18 in the tissue.

19 Is that consistent with your
20 understanding?

21 A. Yeah.

22 MR. SNELL: Form.

23 THE WITNESS: Does it have the potential
24 to do so, based on testing.

25 MR. SLATER: Okay.

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1 BY MR. SLATER:

2 Q. If you go to the third paragraph here, I
3 want to ask you about -- well, rephrase.

4 The third paragraph of this document says,
5 in accordance with the FDA guidance document entitled
6 "Guidance For the Preparation of a Premarket
7 Notification Application For a Surgical Mesh," it is
8 considered that the extensive clinical experience
9 with these devices precludes the need to conduct
10 cytotoxicity. And there's a list of other studies
11 that it's saying we don't have to do those because of
12 the extensive clinical experience with the devices
13 listed above, which were Prolene mesh and Prolene
14 suture.

15 That's what's stated here; correct?

16 A. Yes, it -- it says, in accordance with the
17 FDA guidance, this toxicologist's opinion was, given
18 the extensive track record and understanding of -- of
19 the biocompatibility of polypropylene -- what are his
20 words -- precludes the need to conduct those -- those
21 studies.

22 Q. Let me ask you a question: When -- when
23 Prolene mesh or Prolene Soft mesh erodes through
24 tissue, it is causing damage to the adjoining,
25 adjacent tissue; correct?

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1 MR. SNELL: Form.

2 THE WITNESS: I don't -- I don't know that
3 it's causing damage but the tissue is damaged and
4 the -- and the -- and the -- and the mesh is either,
5 as you say it, eroded or exposed, two different
6 things. So it's either -- it's visible in -- in a
7 lumen or transmucosally.

8 BY MR. SLATER:

9 Q. During the process of mesh erosion or mesh
10 exposure the adjoining tissue is damaged; correct?

11 A. Yeah, I guess -- there's -- there's tissue
12 disruption if -- yeah.

13 Q. Now, would medical affairs -- well,
14 rephrase. Let me take that back. Do you know
15 what -- well, rephrase.

16 Do you know whether or not cytotoxicity
17 testing had been performed on Prolene mesh at any
18 time?

19 A. I don't know.

20 Q. Do you know whether cytotoxicity testing
21 was performed by your company with regard to Prolene
22 suture?

23 A. I believe so.

24 Q. Do you know what the results were?

25 A. If my recollection serves me -- and it may

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1 or may not -- that the results were mixed.

2 Q. Tell me what you mean by that.

3 A. That -- that one study suggested
4 cytotoxicity and one did not.

5 Q. With the Prolene suture?

6 A. Well, Prolene. I don't know if it's
7 Prolene suture, but it was polypropylene.

8 Q. Well, my question is specific. I want to
9 be -- because I want to differentiate --

10 A. Okay.

11 Q. -- so let me ask it clean. Are you aware
12 of testing performed by your company -- rephrase.

13 Are you aware of testing by your company
14 to determine whether there is cytotoxicity with
15 Prolene suture?

16 A. I don't know that.

17 Q. Do you know whether your company performed
18 cytotoxicity testing with Prolene mesh?

19 A. I don't know that.

20 Q. Would you agree with me, if your company
21 had performed cytotoxicity testing with Prolene
22 suture or Prolene mesh and that testing had shown
23 cytotoxicity, that you would have wanted to -- from a
24 medical affairs perspective, would have wanted to
25 have Prolene Soft mesh tested to see what the result

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1 is, as opposed to saying, well, even though there's
2 cytotoxicity that's been proven with one or both of
3 these precursors, we're going to say, well, there's a
4 clinical history that says we don't have to test it?
5 From a medical affairs perspective, you would say,
6 no, you should do the testing on this mesh in that
7 circumstance; correct?

8 MR. SNELL: Form.

9 THE WITNESS: Not necessarily correct, no.
10 I would listen to the advice of the toxicologists and
11 try to understand what they're saying.

12 BY MR. SLATER:

13 Q. Now, the toxicologists in preclinical --
14 that's who your talking about; right?

15 A. Yeah.

16 Q. The toxicologists in the preclinical
17 department are not experts on the clinical
18 significance of their findings. That's not what they
19 are expert in; correct?

20 A. Well, I think they certainly have some
21 expertise but that's not their main area of focus,
22 no.

23 Q. And as your company functions, it's
24 medical affairs that has the -- is looked to for the
25 clinical expertise to say, okay, these are your

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1 preclinical findings but we decide in medical affairs
2 the clinical significance of your findings. Is that
3 a -- is that a correct statement?

4 A. Yeah. It's collaborating with -- with the
5 scientists who understand what -- what the test means
6 when they do them, yeah.

7 Q. So to the extent that Thomas Barbolt from
8 the preclinical department drew any conclusions about
9 whether or not testing was needed or what the
10 clinical significance would be of any testing results
11 that were available, medical affairs would need to
12 look at that and make a decision, well, you know,
13 that's -- we see your opinion but medical affairs has
14 to make an independent judgment on this; correct?

15 MR. SNELL: Form.

16 THE WITNESS: Yeah, I would -- I would
17 expect that those two -- those two functions would
18 work collaboratively around what's -- what's
19 required.

20 BY MR. SLATER:

21 Q. You would expect that the final decision,
22 for example, on whether or not to do cytotoxicity
23 testing on Prolene Soft mesh, that final decision
24 would not be made by somebody in the preclinical
25 department, for example, Tom Barbolt, alone.

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1 You expect that if that decision was made,
2 medical affairs would need to also agree to that
3 decision.

4 MR. SNELL: Form.

5 THE WITNESS: That's an absolute so I --
6 could there be -- could there be times when it's
7 perfectly appropriate for the preclinical person to
8 make such a decision? I think yes, based on their
9 expertise and understanding of what it is they
10 have -- that they're trying to accomplish with their
11 testing.

12 I think if there were questions around the
13 clinical relevance of findings that -- of -- sure,
14 that medical affairs would be involved with those
15 discussions. And if medical affairs felt like this
16 is an unacceptable risk, then they -- they -- they
17 would block the -- the progress.

18 MR. SLATER: Okay.

19 BY MR. SLATER:

20 Q. In this circumstance -- I understand that
21 was a -- I understand generally what you said.

22 A. Yeah.

23 Q. I want to ask a specific question. With
24 regard to Prolene Soft mesh, according to this
25 document, Thomas Barbolt concluded that there was no

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1 necessity to perform cytotoxicity testing.

2 In this context, would you expect that
3 medical affairs would have needed to agree to that
4 decision in order for that testing not to be
5 performed?

6 A. Not necessarily.

7 Q. Let's look at the -- let's look at the
8 conclusion by Thomas Barbolt with regard to Prolene
9 Soft mesh.

10 In summary, the preclinical study
11 results -- and I want to stop there.

12 As we know from what we saw above, the
13 preclinical study results do not include cytotoxicity
14 testing of Prolene Soft mesh because he concluded
15 that didn't need to be done; correct?

16 A. That's what that --

17 MR. SNELL: Form.

18 THE WITNESS: That's what that statement
19 says.

20 MR. SNELL: I don't see what you're
21 talking about.

22 MR. SLATER: Well, I'll just -- I'm happy
23 to clarify with you, Counsel.

24 I've had people search every document
25 produced by your company incessantly for the last few

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1 weeks. Nobody has been able to find any cytotoxicity
2 testing ever performed by your company on Gynemesh
3 Prolene Soft mesh or on Prolene Soft mesh, and what
4 we find -- we have is this document which says that
5 decision was made not to perform that testing.

6 If you can tell me that that testing
7 actually was performed, I'm more than happy to look
8 at it, but this document says the testing was not
9 going to be performed and it provides a rationale and
10 nobody can find it. So unless you have information
11 to the contrary, I don't really understand your
12 objection.

13 MR. SNELL: My objection was I thought
14 your question, you actually said that cytotoxicity
15 wasn't done with Prolene mesh. You didn't specify
16 Prolene Soft.

17 Now, if I misheard you, I misheard you.
18 As to your statement that, to your understanding,
19 regarding Prolene Soft that these weren't done and
20 you haven't found it in the documents, I mean, I
21 can't really comment on that. So I thought I heard
22 you say Prolene mesh, which is a misstatement.

23 MR. SLATER: It is a miss -- that would be
24 a misstatement. We're going to get to that.

25 MR. SNELL: Okay.

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1 MR. SLATER: But that's not what I said.

2 MR. SNELL: Okay.

3 MR. SLATER: I just want to make clear,
4 you're not representing that you're aware --

5 MR. SNELL: I'm not representing anything.
6 I thought I heard you say Prolene mesh.

7 MR. SLATER: No. Slow down. Slow down.
8 I just want to make sure for the record because other
9 people are going to look at this and they're going to
10 rely on this, you're not aware, to the extent this is
11 something we can rely on, obviously, you can go back
12 and say, hey, I found something, you know, it's
13 obviously something you want to look at, but as you
14 sit here now, you're not aware of cytotoxicity
15 testing on Prolene Soft mesh.

16 MR. SNELL: As I sit here now, I haven't
17 searched for that so I can't tell you one way or the
18 other.

19 MR. SLATER: Okay. Okay. Now I have to
20 try to remember my question.

21 Great distraction maneuver, Navy man.
22 Okay.

23 BY MR. SLATER:

24 Q. We know, based on this document, that a
25 decision was made not to perform cytotoxicity testing

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1 on Prolene Soft mesh and a rationale was provided in
2 this document; correct?

3 A. Correct.

4 Q. There was cytotoxicity testing performed
5 on Prolene mesh in connection with the 510(k) for the
6 TVT, and that did actually show on two different
7 cytotoxicity tests, on one marked cytotoxicity, on
8 another severe cytotoxicity.

9 You're aware of that; right?

10 A. Not specifically, no.

11 Q. Is that some -- I got the sense from one
12 of your earlier answers that you were familiar with
13 those test results.

14 A. I couldn't have told you which product it
15 was related to.

16 Q. Okay. I have it, I'll show it to you, and
17 that way I don't want you to have to take my word for
18 anything.

19 A. Okay.

20 MR. SLATER: Got too big for my briefcase.

21 MR. SNELL: Thanks.

22 MR. SLATER: Give me one second. I'll
23 pick out the page. Okay.

24 BY MR. SLATER:

25 Q. What I've handed you is the actual 510(k)

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1 that -- notification that was filed with the FDA
2 regarding the TVT, and it's been marked as Exhibit
3 T-3142 is what I believe it says, at a deposition on
4 August 20, 2013. I'm familiar with it because it was
5 during Mr. Cecchini's deposition that I was involved
6 in.

7 What I want to do is just take you to two
8 specific pages. If you look at the Bates numbers --

9 A. Uh-huh.

10 Q. -- it's 310 and 311 on the bottom right.
11 Those are the last three digits.

12 A. 310?

13 Q. Yeah. There's a number -- there's a Page
14 59 and then the next one is Page 60. Okay.

15 What I'm showing you is cytotoxicity
16 testing on the Prolene mesh. And if you look at this
17 testing, which it says it's using the ISO elution
18 method, at the bottom it says that under the
19 conditions of this study the MEM test extracts were
20 moderately cytotoxic and failed this ISO test.

21 You see that?

22 A. I do.

23 Q. And if you turn to the next page, is the
24 result of another cytotoxicity test of the Prolene
25 polypropylene mesh and the conclusion points out,

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1 under the conditions of this study, the MEM test
2 extracts were severely cytotoxic and failed this ISO
3 test.

4 Do you see that?

5 A. Yes.

6 Q. Okay. And you see who the person is who
7 signed off on both of these in October of 1997?

8 A. Yes.

9 Q. Thomas Barbolt; right?

10 A. Uh-huh. Correct.

11 Q. The same person who signed off on the
12 Prolene Soft mesh biocompatibility risk assessment;
13 correct?

14 A. Correct.

15 Q. And if we look again at the conclusion by
16 Mr. Barbolt, he says, in summary, the preclinical
17 study results -- and I'm going to stop there.

18 According to this document, he decided not
19 to do cytotoxicity testing on Prolene Soft, so that
20 would not be one of the test results available;
21 correct?

22 A. I think it implies that, yes.

23 Q. And I've just shown you the cytotoxicity
24 testing for the Prolene mesh that was submitted to
25 the FDA with the TVT 510(k) that showed on two

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1 different tests moderate and severe cytotoxicity for
2 Prolene mesh.

3 You see that?

4 A. I do.

5 Q. Okay. So he knew that Prolene mesh, based
6 on the result he signed off on, had been found to be
7 cytotoxic; right?

8 MR. SNELL: Form.

9 BY MR. SLATER:

10 Q. That's what the document shows.

11 A. It says, under the conditions of this test,
12 yes.

13 Q. Okay. So let's go further now.

14 In summary, the preclinical study
15 results -- we've talked about that -- and the
16 extensive clinical experience with current Prolene
17 mesh -- and that would be in 1999 the extensive
18 clinical experience with current Prolene mesh, that
19 would be hernia, use for hernia treatment; correct?

20 A. I presume that's what he's relating to.

21 Q. There's not extensive clinical experience,
22 to your knowledge, as of 1999 regarding the use of
23 Prolene mesh --

24 A. Right.

25 Q. -- in the pelvis; correct?

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1 A. Correct.

2 Q. And then he goes further in talking about
3 the extensive clinical experience with Prolene suture
4 is another aspect he's relying on; right?

5 A. Uh-huh.

6 Q. And we can agree, however, that the
7 clinical experience with Prolene suture would not be
8 strongly determinative of what you would expect to
9 happen with the mesh. You would expect that you need
10 to test the mesh separately.

11 A. From a cyto -- I'm not sure that I agree
12 with that from a cytotoxicity standpoint. I -- I
13 would rely on them to say, does the physical
14 construct have anything at all to do with -- with
15 cytotoxicity.

16 Q. I think we spoke about this earlier. To
17 your knowledge, you're not familiar with your company
18 studying Prolene suture with regard to cytotoxicity?

19 A. I don't know, yes or no.

20 Q. Okay. If the testing of Prolene suture
21 showed cytotoxicity on some tests that your company
22 had available to it, that would be something that
23 would, from a medical affairs perspective, militate
24 towards, hey, we should be doing testing on this new
25 mesh; right?

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1 MR. SNELL: Form.

2 Go ahead.

3 THE WITNESS: I'm sorry. Please, one more
4 time.

5 MR. SLATER: Sure.

6 BY MR. SLATER:

7 Q. If testing had been done on the suture --

8 A. Yes.

9 Q. -- Prolene suture --

10 A. Okay.

11 Q. -- for cytotoxicity, if the testing was
12 negative and showed no cytotoxicity, that, from a
13 medical affairs perspective, could have one meaning
14 to you and if cytotoxicity testing of Prolene suture
15 had shown some cytotoxicity, that could have -- lead
16 you to a different conclusion, potentially.

17 A. So --

18 Q. In general terms; right?

19 MR. SNELL: Form.

20 THE WITNESS: -- if the testing had been
21 done in 1960-something, when -- when Prolene came,
22 you know, around as a suture material, you know,
23 the -- the 30- or 40-year history or whatever it had
24 been of clinical use of polypropylene suture in very
25 delicate tissues and in -- in extenuating

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1 circumstances, had it been cytotoxic, I would have
2 known about it.

3 BY MR. SLATER:

4 Q. Your feeling is, from all that you know
5 about Prolene sutures, is that to the extent there's
6 any cytotoxicity that might be shown on a test, in --
7 in the clinical world, it would not be causing any
8 significant issues for any patients.

9 A. Yes.

10 Q. Okay. What Thomas Barbolt, if we continue
11 through this conclusion, after he talks about the
12 preclinical study results, to the extent they
13 existed, the extensive clinical experience, as he
14 calls it, with current Prolene mesh, which we've just
15 talked about, and the clinical experience with
16 Prolene suture, those factors lead him to conclude
17 that they're intrinsically safe and without
18 significant adverse effects for patients.

19 Do you see that?

20 A. Yes.

21 Q. Now, the decision as to whether or not
22 Prolene mesh is intrinsically safe and without
23 significant adverse effects for patients, that is not
24 a conclusion for a preclinical person to be drawing,
25 that's a conclusion for medical affairs to be

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1 drawing; correct?

2 A. I -- I think -- I think they each could
3 make -- could draw their conclusions.

4 I mean, Tom Barbolt with his long history
5 with this material and awareness working in the
6 medical device area for so many years would have a --
7 would have a sense as to whether this was
8 clinically -- had -- had -- had functioned in a
9 clinically safe manner.

10 Q. Let me change the question a little bit.

11 Thomas Barbolt can draw that conclusion
12 but that -- the analysis within your company should
13 not end there. Medical affairs --

14 A. Yeah.

15 Q. -- would also need to draw the same
16 conclusion for that to become the conclusion of your
17 company; correct?

18 A. If there was a difference in opinion, you
19 bet, medical affairs should -- from a medical safety
20 or performance standpoint, they should have the --
21 the trump card, if you will.

22 Q. Well, what I'm asking is, Thomas Barbolt's
23 opinion should not be the only opinion that is
24 documented on this issue. Medical affairs would also
25 need to weigh in and -- and confirm that it also

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1 holds that conclusion if decisions are going to be
2 made based on that conclusion; correct?

3 A. I don't know that the process would --

4 MR. SNELL: Form.

5 Go ahead.

6 THE WITNESS: -- would bring medical
7 affairs in at that stage.

8 BY MR. SLATER:

9 Q. Well, let me ask you this: In your
10 company decisions as to whether or not a mesh
11 material is intrinsically safe and without
12 significant adverse effects for actual patients in
13 the actual clinical world, that's a decision medical
14 affairs ultimately needs to make.

15 There can be input from preclinical --

16 A. Right.

17 Q. -- there can be input from other people
18 but the ultimate decision that your company is going
19 to rely on, medical affairs has to make that final
20 decision; correct?

21 A. Yeah, for any -- any product in development
22 before it can go out the door, medical affairs would
23 have to sign off on essentially a benefit-risk
24 analysis, and this would be one of the inputs.

25 I don't think they would sign -- I'm sure

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1 they don't sign off on a -- on a preclinical or
2 biocompatibility of a next-generation plan, if you
3 will.

4 Q. Just --

5 A. But they --

6 MR. SLATER: Move to strike from "I'm
7 sure" forward.

8 Went a little beyond what I was talking
9 about but I understand what you're saying.

10 BY MR. SLATER:

11 Q. Tell me if I understand. Preclinical will
12 make its own decisions in the first instance about
13 what testing is needed and what conclusions can be
14 drawn from the perspective of the preclinical people.

15 A. Correct.

16 Q. The significance of those conclusions for
17 actual patient and benefit-risk analysis and whether
18 or not something is actually going to be safe and
19 acceptable in use of a patient, that ultimate
20 decision is medical affairs'; correct?

21 A. Uh-huh. That's correct.

22 Q. Tom Barbolt concluded, it is considered
23 that soft Prolene mesh manufactured with a portion of
24 blue filaments will result in the same level of
25 safety demonstrated by the currently marketed

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1 products and no further clinical -- preclinical
2 testing is necessary.

3 That was his final conclusion; right?

4 A. Right.

5 Q. He was relying on the first part of that
6 paragraph, obviously, where he's relying on the
7 clinical experience with the use of Prolene mesh and
8 Prolene suture; correct?

9 A. In part, yeah.

10 Q. So you would agree with me that to make
11 that decision that further preclinical testing is not
12 needed, based on what's happened in the clinical
13 world, medical affairs would also need to confirm,
14 yes, you can draw that conclusion, we confirm that
15 this is what's going on in the real clinical world
16 and that is reliable to say we don't have to do any
17 more testing.

18 A. So as a matter of process, during
19 development, the -- the -- you know, the -- the risk
20 management program would include medical affairs at
21 every stage along the way saying, yes, I believe that
22 we're on track with -- with producing a safe and
23 effective product.

24 I don't believe they would necessarily
25 individually have to sign off on a document saying I

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1 agree with that conclusion but at the -- at the end
2 of the day, there is a -- a final sign-off where the
3 physician would have to say, given all the
4 information we have, I believe that we have a safe
5 and effective product and we should move forward, the
6 benefit-risk is satisfactory or appropriate.

7 Q. You would certainly agree with me that in
8 the context of this document and the ultimate
9 sign-off on Prolene Soft mesh, that medical affairs
10 would have needed to be aware of this analysis by
11 Thomas Barbolt and would have needed to be in
12 agreement in order to go forward in reliance on his
13 opinion.

14 A. Yeah, I think they would have had some
15 visibility and been in alliance. Yeah.

16 Q. If medical affairs didn't see this and
17 wasn't aware of it, that would be -- that would be a
18 bad miss; right?

19 MR. SNELL: Form.

20 BY MR. SLATER:

21 Q. Let me rephrase it because that's a little
22 too colloquial for us.

23 If medical affairs never saw this
24 document, that would be -- that would be a breakdown
25 in how the system is supposed to work because medical

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1 affairs is supposed to be aware of this document?

2 MR. SNELL: Form.

3 THE WITNESS: I don't know about being
4 aware of the document. They would certainly be part
5 of the discussions, be aware of the decision, I would
6 think. I don't know about the document.

7 BY MR. SLATER:

8 Q. Let me ask it more directly, then. The
9 way the system works, medical affairs would need to
10 know that this decision was made by Tom Barbolt and
11 medical affairs would need to agree with that
12 decision for the company to rely on that decision.

13 A. Yeah.

14 Q. Correct?

15 A. Yeah.

16 Q. Okay.

17 MR. SLATER: Why don't we take a break. I
18 need a drink and probably a good time.

19 VIDEO OPERATOR: The time is now 11:41.

20 This the end of Disk Number 2.

21 We are going off the record.

22 (Recess, 11:41-12:03 p.m.)

23 VIDEO OPERATOR: The time is now 12:03.

24 This is the beginning of Disk Number 3.

25 We are back on the record.

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1 BY MR. SLATER:

2 Q. Dr. Hart, to your knowledge, has anybody
3 in Ethicon medical affairs ever tried to correlate
4 cytotoxicity testing of Prolene Soft mesh with the
5 clinical risk-benefit profile for Prolene Soft mesh?
6 Did that ever happen, to your knowledge?

7 A. I don't know.

8 Q. Did you ever hear of that happening? Are
9 you aware of it ever happening?

10 A. No.

11 Q. In all the time that you've been with
12 Ethicon -- and I'm talking now with regard to Prolene
13 Soft mesh, Gynemesh PS, the Prolift, the Prolift+M,
14 the Prosima, all of the pelvic mesh devices for
15 prolapse -- was there ever any discussion or
16 documentation you're aware of where the subject of
17 cytotoxicity was even mentioned?

18 A. I don't know yes or no.

19 Q. Okay.

20 A. I mean I --

21 Q. Nothing you're aware of.

22 A. No.

23 Q. Okay. Now, what I'd like to do -- let me
24 ask you this, a more narrow question: With regard to
25 the Prolift, to your knowledge, has anybody in

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1 Ethicon medical affairs ever considered the subject
2 of whether or not the material is cytotoxic, to your
3 knowledge?

4 A. I don't know yes or no.

5 Q. Nothing you're aware of.

6 A. Correct.

7 Q. Okay. If you could look back at the TVT
8 510(k), I have a -- I want to ask you about
9 something. There are page numbers in the bottom
10 right, and I'll go by the page number. It's Page 40.

11 A. Okay. Not okay.

12 Q. At the top of the page in the left margin
13 it shows that this section of the 510(k) addresses
14 biocompatibility testing.

15 You see that? Left column.

16 A. Yes.

17 Q. At the very bottom of the page it says,
18 the long clinical experience with Prolene mesh
19 indicated that the cytotoxicity testing would be
20 sufficient to support biocompatibility of this
21 component.

22 And so that's talking about the mesh
23 there; right?

24 A. I don't quite understand the sentence. A
25 long --

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1 Q. One of the components -- let me ask it
2 differently: One of the components of the TVT is the
3 mesh.

4 A. Yes.

5 Q. Okay. And this indicates, the long
6 clinical experience with Prolene mesh indicated the
7 cytotoxicity testing would be sufficient to support
8 biocompatibility of this component.

9 That's what it states here in the 510(k);
10 right?

11 A. Yes.

12 Q. So what this is saying is, your company
13 took into account the long clinical experience with
14 Prolene mesh. I want to stop there.

15 That would be with Prolene mesh for use
16 for hernia because as of the time that this was
17 submitted in October 1997, there was no long clinical
18 history of using Prolene mesh in the female pelvis;
19 right?

20 MR. SNELL: Form.

21 THE WITNESS: I guess we have to define
22 what long term would mean, but certainly had been
23 used in -- in female surgery before -- this is 1998?

24 MR. SLATER: It was filed in 1997 --

25 THE WITNESS: Yeah.

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1 MR. SLATER: -- and cleared in early 1998.

2 THE WITNESS: Yeah.

3 So we know that the -- the company that
4 was -- was developing TVT had data, longer than --
5 not five-year data but that was used in the female
6 pelvis, yes.

7 BY MR. SLATER:

8 Q. Based how you would define a long clinical
9 experience, there was not a long clinical experience
10 using Prolene mesh to treat pelvic floor conditions
11 as of 1997, 1998; correct?

12 MR. SNELL: Form.

13 Go ahead.

14 THE WITNESS: How I would define long-term
15 use. Certainly -- certainly, we've seen, quote,
16 long-term results stated at a year or two years.
17 Certainly, there was not five-year data.

18 BY MR. SLATER:

19 Q. The long clinical experience with Prolene
20 mesh was overwhelmingly hernia. There might have
21 been some usage in the female pelvis but the vast,
22 vast majority of that would have been hernia;
23 correct?

24 A. I don't know the numbers, but yes.

25 Q. Okay. And what this is saying is --

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1 rephrase.

2 What this is saying is that, based on the
3 long clinical experience with Prolene mesh, whatever
4 that experience was, the decision was made to do
5 cytotoxicity testing and that would establish the
6 biocompatibility; right?

7 A. I'm -- I actually don't know. I'd have to
8 read a lot more, I think, to understand what it is
9 he's exactly saying or the --

10 Q. Well, this statement in and of itself is
11 indicating that, based on the clinical experience
12 with Prolene mesh, we've made a decision to do
13 cytotoxicity testing to determine the
14 biocompatibility.

15 That's what it says; right?

16 A. That's what it -- that's what it looks
17 like, yeah.

18 Q. I've shown you cytotoxicity test results
19 showing in one test severe cytotoxicity.

20 I showed you those a few moments ago;
21 right?

22 A. You did.

23 Q. Go to the next page, Page 41. At the very
24 bottom of the page it indicates, however -- well,
25 rephrase.

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1 At the bottom of Page 41 now, still in the
2 biocompatibility testing section, it indicates that
3 the mesh was cytotoxic on the elution test,
4 suggesting cytotoxic potential in the sensitive test
5 system.

6 See that?

7 A. No, not yet.

8 Q. It's the very bottom of the page.

9 A. Okay.

10 Q. The last paragraph.

11 A. I'm going to read the whole way down.

12 Okay.

13 Q. Okay. Not even sure what I asked so I'll
14 ask a new question.

15 At the bottom of Page 41 it indicates that
16 cytotoxicity testing was positive on one of the
17 tests, the elution test; right?

18 A. Yes.

19 Q. And I showed you that a little while ago;
20 right?

21 A. Uh-huh.

22 Q. And then he says, however, the long
23 history of safe clinical use of polypropylene as mesh
24 and suture products suggests strongly that this
25 material is inherently biocompatible and that the

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1 potential cytotoxicity observed is self-limiting and
2 minimal when compared to the implantation procedure
3 itself.

4 So that was what was concluded here;
5 right?

6 A. Yes.

7 Q. Now, what we basically have here, though,
8 if you -- if you combine what was at the bottom of
9 Page 40 with the bottom of Page 41 is a decision was
10 made, based on the long clinical experience with
11 Prolene mesh, we think that cytotoxicity testing is
12 what we should use to determine biocompatibility.

13 That's what it says on Page 40; right?

14 A. Uh-huh.

15 Q. Then we turn to the bottom of Page 41 and
16 they say, well, the cytotoxicity testing that we
17 performed actually showed moderate and severe
18 cytotoxicity.

19 I showed you those documents earlier;
20 right?

21 A. Yes.

22 MR. SNELL: Form.

23 Go ahead.

24 BY MR. SLATER:

25 Q. But we're going to say, because of the

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1 long clinical experience, we can discount those tests
2 and determine that this will actually be a
3 self-limiting and minimal issue.

4 That's the -- what's finally concluded
5 here; right?

6 A. Well, I think they -- they clarify it above
7 a little bit more than that by saying the
8 polypropylene mesh component is sterile TVT device
9 was cytotoxic only in the elution testing because
10 they describe up above here some other -- other
11 testing that was less with -- with different results.

12 Q. If you go to the very top, there were two
13 types of cytotoxicity testing, and on the elution
14 testing it showed polypropylene mesh to be moderate
15 to severe cytotoxicity.

16 Do you see that?

17 A. Yes.

18 Q. So what ultimately happened here is, the
19 document shows that your company said, okay, we have
20 a history of use of the Prolene mesh, based on that
21 clinical history, we think we need to do cytotoxicity
22 testing to determine biocompatibility.

23 A. Uh-huh.

24 Q. The testing is done and on one set of
25 tests showed cytotoxicity that's described as severe

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1 on one of the tests, which would indicate questions
2 or issues with biocompatibility in and of itself;
3 right?

4 MR. SNELL: Form.

5 Go ahead.

6 THE WITNESS: I think you'd have to
7 interpret the results of that test in the total
8 context but, yeah, that's part of the input when you
9 make the biocompatibility determination.

10 BY MR. SLATER:

11 Q. And then he comes all the way full circle
12 and says, well, we're going to discount that finding
13 because of the history of clinical use of the mesh.

14 Isn't that circular?

15 A. No. Because I think he talks about this
16 only in this sensitive test. He describes other
17 tests up here where cytotoxicity was not demonstrated
18 and he's -- I believe he's concluding with the long
19 clinical use, history of use, and my understanding of
20 his understanding of these tests, he feels that it's
21 biocompatible.

22 Q. Medical affairs would need to weigh in on
23 that type of a decision; right?

24 MR. SNELL: Form.

25 THE WITNESS: Medical affairs would be --

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1 yeah, would -- would see a -- a 510(k) submission.

2 BY MR. SLATER:

3 Q. Medical affairs would need to agree that
4 you could discount the cytotoxicity test results
5 based on the clinical history.

6 That would -- that -- medical affairs
7 would need to sign off on that type of a decision;
8 right?

9 A. Medical affairs would have to, yes, work
10 with the toxicologist to understand the implications
11 of the testing that was done, put it in perspective
12 and say, yes, I believe that the 510(k) submission
13 supports safe and effective use.

14 Q. If medical affairs didn't do that, that
15 would be a breakdown in the system, to that extent,
16 if medical affairs didn't review this finding and
17 agree with it before this was submitted; right?

18 MR. SNELL: Form.

19 THE WITNESS: If medical affairs wasn't
20 part of the team submitting the 510(k) -- medical
21 affairs is part of the team submitting the 510(k).

22 BY MR. SLATER:

23 Q. My question is this: If medical affairs
24 didn't actually review this finding and agree with
25 it, your company should not have been going forward

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1 in reliance on this without medical affairs actually
2 being in agreement.

3 A. Yeah, as part of the overall risk
4 evaluation of the product, they would have visibility
5 to this information. Yes.

6 Q. Now, in terms of cytotoxicity -- I think
7 we talked about this earlier -- one manifestation of
8 cytotoxicity in a clinical environment with Prolene
9 mesh would be if the mesh eroded through the vaginal
10 wall and was exposed; right?

11 MR. SNELL: Form.

12 Go ahead.

13 THE WITNESS: Yeah. I'm sorry. Just
14 answer -- ask it one more time, please.

15 MR. SLATER: Sure.

16 BY MR. SLATER:

17 Q. One clinical example of a clinical
18 manifestation of cytotoxicity would be if Prolene
19 mesh were to erode through the vaginal wall and be
20 exposed into the vagina; right?

21 MR. SNELL: Form.

22 THE WITNESS: If a material is implanted
23 and it is cytotoxic, it could result in tissue damage
24 such that it would be exposed.

25 BY MR. SLATER:

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1 Q. Now, if you could, turn to Page 87. Well,
2 actually, first turn to Page -- because I want you to
3 see what you're reading -- Page 83.

4 Page 83 is the clinical report for the
5 clinic, the Scandinavian multi-center study of the
6 TVT which was performed by Medscan, Dr. Ulmsten, et
7 cetera; correct?

8 A. Yes.

9 Q. And if you turn now to Page 87 within the
10 document, where they're talking about the results,
11 the third paragraph I want to ask you about. It says
12 that there was a patient who required surgical
13 intervention with resection of exposed mesh.

14 Do you see that? Third paragraph, very
15 bottom.

16 A. Yes.

17 Q. Would an erosion of the mesh through the
18 vaginal wall such that it was exposed be considered
19 an example of impaired wound healing as a result of
20 the interaction of the mesh and the tissue?

21 A. Oh, it certainly would be an example of --
22 of impaired wound healing. I don't know that you
23 could logically or immediately draw the conclusion it
24 was an interaction between the mesh and the tissue
25 that caused that.

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1 Q. The mesh in the TVT causes a foreign body
2 reaction with the tissue around it; correct?

3 A. Yes.

4 Q. And overt evidence of that foreign body
5 reaction would be if you looked at pathology slides
6 and saw inflammatory cells; correct?

7 A. Yeah, that -- that would be a finding of a
8 foreign body reaction. Yes.

9 Q. Overt clinical evidence of a foreign body
10 reaction would be if the mesh actually eroded through
11 the vaginal wall and was exposed into the vagina;
12 correct?

13 A. No.

14 Q. You don't -- you don't believe that
15 erosions occur, in part, as a result of the foreign
16 body reaction?

17 A. I don't think it's necessarily one leads to
18 the other.

19 Q. You would agree with me that, I'm not
20 going to come up with percentages with you, but there
21 are instances known and your company would agree and
22 you would agree that erosions can occur as a result
23 of the foreign body reaction leading to the mesh
24 eroding and exposing through the vaginal wall;
25 correct?

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1 A. No, I don't know that I know that, that
2 it's the foreign body reaction that causes erosion.
3 I don't know that.

4 Q. Okay. If a woman has inflammation -- has
5 a foreign body reaction -- well, rephrase.

6 Overt evidence of the foreign body
7 reaction between the TVT mesh and the tissue around
8 it would be the inflammation, the forming of
9 fibrosis, and in some women contraction of the mesh
10 by the scar tissue that forms; correct?

11 MR. SNELL: Form.

12 THE WITNESS: Correct.

13 BY MR. SLATER:

14 Q. Other overt evidence would be if that were
15 to occur and lead to pain and the patient actually
16 felt pain; correct?

17 A. Could -- yeah, the pain could be related to
18 the contraction.

19 Q. If you could, turn back to Page 42.

20 MR. SNELL: Page 42, you said?

21 MR. SLATER: Yes.

22 BY MR. SLATER:

23 Q. This is -- again, this is the last page of
24 the biocompatibility testing results section of the
25 510(k) for the TVT.

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1 A. Okay.

2 Q. And this is discussing clinical data with
3 regard to the TVT at the very top.

4 Do you see that? I just want to make sure
5 we're oriented to the same location.

6 A. 42 says, biocompatibility testing results
7 continued, on the upper left?

8 Q. Yeah. Yes.

9 Now, at the very top it says that the use
10 of the TVT device, which includes the implanted
11 polypropylene mesh, has fewer complications in terms
12 of tissue reaction than other comparable devices.

13 Do you see that?

14 A. I do.

15 Q. Do you know -- do you have any idea what
16 other comparable devices are being referred to here?

17 A. I don't.

18 Q. Knowing the history of the use of
19 polypropylene mesh in the TVT and what other devices
20 were available, was there another comparable device
21 at that time that you're aware of?

22 A. I won't -- I won't present -- pretend to
23 know that explicitly, no.

24 Q. I will tell you, the predicate device for
25 the TVT, as stated in this 510(k), was a Boston

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1 Scientific urinary incontinence, stress urinary
2 incontinence, product called the ProteGen Sling.

3 Are you aware of that?

4 A. Vaguely, yes.

5 Q. Would that be one of the comparable
6 devices or do you not know?

7 A. I -- I don't know what they were referring
8 to here.

9 Q. It says here a little further down,
10 implantation -- let me just reorient.

11 Here on the -- on Page 42, the last page
12 of the biocompatibility testing results section, it
13 states, implantation of a potentially cytotoxic
14 material would be expected to cause impaired wound
15 healing, resulting in non-healing ulcerations and
16 overt evidence of foreign body reaction.

17 Do you see that?

18 A. I do.

19 Q. And I think we just established a few
20 moments ago that there are examples of overt evidence
21 of foreign body reaction with the TVT; correct?

22 A. Well, so I don't know. I mean, I just
23 don't know. Do we have -- do we have clinical
24 histologic evidence of overt -- what do they call it?
25 Overt -- where is it? Overt evidence of foreign body

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1 reaction from a TVT device? I just don't know that.

2 Q. Well, you agree with me that if you could
3 see on pathology slides chronic inflammation, that
4 would be overt evidence of the foreign body reaction;
5 correct?

6 A. I don't know what overt evidence it would
7 be, but yes, inflammatory cells in and around a
8 foreign body is part of a foreign body reaction, yes.

9 Q. And we talked about a few other examples a
10 few moments ago where the scar tissue formed would
11 lead to a contraction of the mesh and it could also
12 lead to pain.

13 That would be overt evidence; correct?

14 MR. SNELL: Well, form.

15 THE WITNESS: So --

16 BY MR. SLATER:

17 Q. We just established that a few moments
18 ago; right?

19 MR. SNELL: Form.

20 THE WITNESS: Scar contracture --

21 MR. SNELL: Go ahead.

22 THE WITNESS: Scar contracture -- I mean,
23 the -- the development of scar tissue or fibrotic
24 tissue is a later-stage event in a foreign body
25 reaction and, indeed, we're aware that scars

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1 contract, and if the scar is and fibrotic tissue is
2 enveloping a foreign body that is compressible, it
3 can be compressed.

4 BY MR. SLATER:

5 Q. According to what it states here in the --
6 in the 510(k) for the TVT, that would be consistent
7 with the cytotoxic property of the material leading
8 to tissue damage --

9 A. Well --

10 Q. -- and a tissue reaction; correct?

11 MR. SNELL: Form and foundation.

12 THE WITNESS: I don't understand your
13 question. Sorry. I missed it.

14 BY MR. SLATER:

15 Q. Based on what it states here, the -- this
16 overt evidence of a foreign body reaction is what one
17 would expect to see as a result of a cytotoxic
18 material.

19 That's what it states --

20 A. Yeah.

21 Q. -- right here; right?

22 A. Yeah. So --

23 MR. SNELL: Form.

24 Go ahead.

25 THE WITNESS: -- a cytotoxic material

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1 implanted in the body and that examined
2 histologically, I would expect a foreign body
3 reaction to be part of the findings.

4 BY MR. SLATER:

5 Q. The other example that's provided here is
6 impaired wound healing, resulting in a non-healing
7 ulceration.

8 When the TVT mesh erodes through the
9 vaginal wall, that's an example of impaired wound
10 healing, resulting in a non-healing ulceration
11 because the mesh is coming through; correct?

12 A. So if you -- if you had a material that was
13 clinically relevantly cytotoxic and you implanted it
14 and that cytotoxicity was of a magnitude that could
15 impair wound healing, then yes, you could have -- you
16 could have loss of tissue over that implant.

17 Q. That's what happens when the mesh of the
18 TVT erodes through the vaginal wall; correct?

19 A. As I said before, I don't know that that's
20 what -- I don't know that that erosion is directly
21 related to a foreign body reaction.

22 Q. Well, you would agree -- I think what
23 you're saying is in all instances you can't say that?

24 A. Well, in all instances I know that's not
25 true.

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1 Q. Okay. You would agree with me that in
2 some instances of TVT erosions through the vaginal
3 wall that that is what occurs; correct?

4 MR. SNELL: Form.

5 THE WITNESS: No. I think you're trying
6 to get me to say that it's cytotoxic and, therefore,
7 causes erosion, and I'm not agreeable to that.

8 BY MR. SLATER:

9 Q. What I'm -- what I'm asking you to agree
10 to is, in some patients the mesh erodes through the
11 vaginal wall and it would be accurately described as
12 an impaired wound healing situation, resulting in a
13 non-healing ulceration.

14 A. That's true.

15 Q. Okay. If it was the conclusion of the
16 people who handled this situation -- well, rephrase.

17 If it was the conclusion of your company
18 at the time the TVT was being developed and clearance
19 was being sought that they didn't have to be
20 concerned about the cytotoxicity test results and
21 they were basing that on some assumption that the TVT
22 mesh would not erode through the vaginal wall and
23 become exposed into the vagina, if that was one of
24 the assumptions that supported that decision, that
25 would be poor logic because that's something that's

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1 known to occur; correct?

2 MR. SNELL: Form.

3 THE WITNESS: You've got to do that one
4 again. Sorry.

5 MR. SLATER: I'm so glad you said that
6 because I don't even know what I'm --

7 BY MR. SLATER:

8 Q. If medical affairs -- well, rephrase.

9 If the people who decided that the
10 cytotoxicity testing didn't -- didn't have to be a
11 concern were relying, in part, on an assumption that
12 the TVT mesh would not erode through the vaginal wall
13 to be exposed into the vagina, if they actually drew
14 that assumption to support that decision, you would
15 disagree with the assumption and you would disagree
16 with the decision; correct?

17 MR. SNELL: Form.

18 Go ahead.

19 THE WITNESS: Well, what -- what's the
20 assumption?

21 MR. SLATER: Okay. I'm going to ask it
22 again.

23 BY MR. SLATER:

24 Q. It would not be accurate to assume that
25 the TVT mesh does not in some women erode through the

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1 vaginal wall and become exposed into the vagina;
2 right?

3 A. It would not be accurate to say that
4 that -- that the TVT tape implanted could not ever
5 become exposed.

6 Q. Okay. If somebody did assume that or your
7 company assumed that at the time the TVT was being
8 developed and first marketed and that that assumption
9 was the basis to say we don't have to worry about the
10 cytotoxicity testing, from a medical affairs
11 perspective, you would criticize the assumption and
12 you would say that that is not a sound basis on which
13 to discount the cytotoxicity.

14 MR. SNELL: Form.

15 THE WITNESS: I think that's accurate.

16 MR. SLATER: Okay.

17 Do you know what time it is?

18 THE WITNESS: Lunchtime.

19 MR. SLATER: I promised that, so okay,
20 let's take a break.

21 VIDEO OPERATOR: Time is now 12:29.

22 We're going off the record.

23 (Luncheon recess, 12:29-1:44 p.m.)

24 AFTERNOON SESSION

25 VIDEO OPERATOR: The time is now 1:44.

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1 We are back on the record.

2 MR. SLATER: Okay.

3 BY MR. SLATER:

4 Q. If you could, turn in the 510(k) to Page
5 87, which is the conclusion to the multi-center trial
6 on the TVT prototype by Medscan.

7 A. Got these upside down. Okay. 87?

8 Q. 87, the very bottom of the page, there's
9 conclusions and discussion.

10 A. Uh-huh.

11 Q. At the very bottom of the page it says --
12 rephrase.

13 In the conclusion and discussion to the
14 Medscan multi-center study they say, also noteworthy
15 is the fact that no cases of graft rejection was seen
16 in this series. Normally, one would expect on the
17 order of a 3 percent rejection rate with traditional
18 slings, as evidenced by vaginal urethral erosion.

19 Do you see where I'm reading?

20 A. Yes.

21 Q. So in terms of how the term "rejection" is
22 being used in this study, apparently, that's being
23 equated to some sort of a reaction between the mesh
24 and the tissue that leads to an erosion either
25 through the vagina or into the urethra or another

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1 part of the body.

2 That's what it seems to be saying there;
3 right?

4 A. No. I think it's saying that -- that
5 when -- when devices like this are used in that
6 setting, they can't -- I don't think it's necessarily
7 a reaction, but this procedure with these devices in
8 place can result in an erosion or in an exposure.

9 Q. Okay. I want to start off with the -- the
10 concept of graft rejection.

11 They are saying here -- it seems to me
12 they're saying when a rejection, however they define
13 that, occurs, the evidence of it would be an erosion
14 either through the vagina, the urethra or someplace
15 else in the pelvis.

16 A. That's what it sounds like when they --
17 yeah, they way they write it. Uh-huh.

18 Q. Okay. They say here that, in the very
19 beginning of that paragraph, there were no cases of
20 that occurring; right?

21 A. Yes.

22 Q. If you go back up just above the
23 conclusions and discussion -- we talked about this
24 earlier -- they talk about resection of exposed mesh.

25 So that would actually have been an

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1 erosion through the vaginal wall that led to exposure
2 and led to the need to resect it; correct?

3 MR. SNELL: Form. Foundation and form on
4 that.

5 THE COURT REPORTER: I'm sorry, Burt.

6 MR. SNELL: Foundation as well on that.

7 THE WITNESS: Well, they describe this --
8 this particular incident as an infection and that
9 required for its treatment, I presume, surgical
10 intervention with resection of exposed mesh.

11 BY MR. SLATER:

12 Q. They talk about the fact in the last
13 paragraph -- well, rephrase -- in the second
14 paragraph of the conclusion that there were no cases
15 of vaginal or urethral erosions; right?

16 A. They just say nowhere there's -- in fact,
17 there were no cases of graft rejection seen in this
18 series.

19 Q. They say there were no cases of graft
20 rejection which would have been evidenced by vaginal
21 and urethral erosion.

22 A. So they're clearly -- they're clearly
23 blaming this erosion that they talk about up above on
24 an infection.

25 Q. We're going to get to that. We're going

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1 to get to the logic of that, but I just want to start
2 by defining what they are saying.

3 In the second paragraph of the conclusion
4 here Dr. Eriksson, who signed the document for
5 Medscan, says there were no cases of graft rejection
6 and in the second -- in the next sentence says
7 evidence of a graft rejection would have been a
8 vaginal or urethral erosion; correct?

9 A. As evidenced by a vaginal -- so yes. So
10 he's saying --

11 Q. He's saying that didn't happen.

12 A. He's saying they didn't have a rejection
13 that resulted in a vaginal or urethral erosion.
14 That's what they're -- that's my read.

15 Q. We can agree that just above the
16 conclusion there is documentation that mesh had
17 eroded through the vaginal wall and become exposed.

18 That's documented right there; correct?

19 MR. SNELL: Form.

20 THE WITNESS: In the patient that had the
21 infection, yes.

22 MR. SLATER: Move to strike.

23 BY MR. SLATER:

24 Q. That is documented there; correct?

25 MR. SNELL: Same objection.

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1 BY MR. SLATER:

2 Q. I'm not asking about the -- we're going to
3 get to that.

4 My question is limited to this: Just
5 above the conclusion it's documented that there was
6 mesh that eroded through the vaginal wall, was
7 exposed and had to be resected.

8 A. Yes.

9 Q. Now, the authors of this study -- and Dr.
10 Eriksson signed it -- claim that there was a vaginal
11 infection that required surgical intervention with
12 resection of exposed mesh; right?

13 A. Right.

14 Q. You know, in fact, that when you have mesh
15 that's exposed into the vagina and is infected,
16 that's something that can happen with a vaginal
17 erosion.

18 MR. SNELL: Form.

19 THE WITNESS: Yes.

20 BY MR. SLATER:

21 Q. When you put all this together, when the
22 authors suggest that there were no cases of graft
23 rejection, which they say would have been evidenced
24 by a vaginal erosion, when you look at just above the
25 conclusions, that does not seem to be consistent with

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1 what it says actually occurred to one patient; right?

2 A. I don't agree with that. I think clearly
3 when I read this, whoever authored it is saying that
4 one patient had an infection and also as a result of
5 the infection had an erosion. He's -- they're --
6 they're claiming here that there weren't any, quote,
7 rejections that resulted in erosion. They're
8 implying two mechanisms for exposure.

9 Q. Okay. Let's put aside the word
10 "rejection" for a second.

11 You would agree with me that, based on
12 what you're reading right here on this last -- these
13 last two pages of this report of this study by
14 Medscan, there was a vaginal erosion that led to
15 exposure of the mesh into the vagina. That's
16 documented.

17 A. There was --

18 MR. SNELL: Form. No. Form.

19 THE WITNESS: There was a vaginal
20 infection and as part of that there was an erosion,
21 according to their -- their opinion.

22 BY MR. SLATER:

23 Q. Frankly, it doesn't matter why the erosion
24 occurs, it just matters that it occurred; right?

25 A. I suspect there are differences in -- in --

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1 in causation that could imply or could impact
2 treatment but an erosion is an -- or an exposure is
3 an exposure, yes, so we --

4 Q. And, in fact, there would really be no way
5 for these doctors to know, did the infection occur
6 before the erosion or did it occur after the erosion.
7 There's no way to know that.

8 MR. SNELL: Form. Objection. Foundation.

9 THE WITNESS: Well, I don't know the
10 circumstances, but I would disagree.

11 If you were following a patient and you
12 saw a wound infection that had subsequently broke
13 down and became an exposure, then their opinion would
14 be the infection came first.

15 BY MR. SLATER:

16 Q. A -- rephrase.

17 An erosion of TVT mesh can occur in the
18 setting of an infection; right?

19 A. They claim so, yeah. Claim so right here,
20 yeah.

21 Q. And you would agree with that; right?
22 That can occur; right?

23 A. I would think so, yeah.

24 Q. One -- one question about something we
25 talked about earlier. Well, rephrase. Let me ask

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1 you this: You would count -- rephrase.

2 If you were asked, is this adverse event
3 that's being described here a vaginal mesh erosion
4 with exposure, would you agree with that?

5 A. I would agree with it -- there was -- this
6 patient had exposed mesh, yes, as part of her
7 clinical course.

8 Q. We spoke a little bit earlier about the
9 reliance by your company on the history of the use of
10 Prolene mesh for hernia treatment. We talked about
11 that a little earlier?

12 A. We did.

13 Q. I've seen documents in various PowerPoints
14 from your company that medical affairs were involved
15 in where they actually say the vagina is not the
16 abdomen nor is it similar to any other surgical
17 environment.

18 Are you familiar with those statements?

19 A. Not off the top of my head, no.

20 Q. You would agree with that premise;
21 correct?

22 A. Yes.

23 Q. So when -- so rephrase.

24 In terms of looking at the history of the
25 use of Prolene mesh in order to get some idea of what

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1 can we expect to happen when we use this mesh in the
2 vagina, you can, your company can look at what occurs
3 and what's known about what occurs in hernia
4 applications but, ultimately, medical affairs and
5 your company would also know, hey, we have to do our
6 own evaluation of what happens in the vagina because
7 it's a very different environment and we cannot
8 expect everything that occurs in abdominal treatment
9 to translate directly to vaginal and pelvic
10 treatment. Is that a fair statement?

11 MR. SNELL: Form.

12 Go ahead.

13 THE WITNESS: I would certainly agree
14 that -- so the -- the experience in the abdomen or
15 in -- in abdominal wall surgery is relevant but
16 not -- but not necessarily completely predictive
17 because they are two different anatomic areas.

18 MR. SLATER: I think there's a fair chance
19 that I'm not going to pull out the 510(k) again. I
20 think we've gone through that part of the
21 questioning.

22 THE WITNESS: I'm sure I have the pages
23 out of order by now, by the way, so -- if anybody
24 cares.

25 MR. SLATER: Well, you know it's a good

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1 document because it contains a lot of data and a lot
2 of other important documents, so rather than bringing
3 them all, I figured bring the big one, bring the
4 honcho. Okay.

5 BY MR. SLATER:

6 Q. I'll hand you, and I have one for
7 counsel -- I just handed you Exhibit T-1338. This is
8 an E-mail that was written by a marketing person
9 within Ethicon, Barbara McCabe, dated April 13, 2005.

10 Do you see that in front of you?

11 A. I do.

12 Q. I want to ask you about a little bit of
13 the language of this E-mail in the first paragraph.
14 She's talking about what she calls a one-pager. That
15 would be a one-page sales aid, something to give to
16 doctors.

17 You see that?

18 A. I do.

19 Q. And she says -- rephrase.

20 And she's talking about in this instance
21 the introduction of a new sheath that they want to
22 promote to doctors through this sales tool, through
23 this one-pager; right?

24 A. Yes.

25 Q. And she says the following: The idea is

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1 to really play up this change and make it sound like
2 a major improvement without actually having any data
3 to prove this, thus, my deliberate use of the words
4 "designed to." This language just means that it was
5 designed to do something, not that it actually does
6 something. And then she says in parentheses,
7 typically, I use this when there is no data, with two
8 exclamation points. I've gotten this through legal
9 before.

10 Do you see where I just read?

11 A. I do.

12 Q. And this E-mail was forwarded to multiple
13 people in marketing, including Dharini Amin, Kevin
14 Mahar and some others there.

15 Do you see that?

16 A. Yes.

17 Q. If you could, can you turn now again to
18 Exhibit 243, the sales aid from the Prolift+M.

19 A. Okay.

20 Q. And if you look at the second-to-last
21 page, I want to ask you a question. On the
22 second-to-last page of this sales aid for physicians
23 it talks about the Gynecare Prolift+M and then it
24 says, in your hands, and it uses the phrase "designed
25 to."

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1 Do you see that?

2 A. Uh-huh.

3 Q. And that's the phrase that was being
4 described by Barbara McCabe in her E-mail, from
5 marketing; right?

6 A. Yes.

7 Q. And she talks about the Prolift+M designed
8 to resist wrinkling and folding, provide anatomic
9 coverage, offer patient-specific adjustability.

10 Do you see that?

11 A. I do.

12 Q. And then on the right-hand side it says,
13 in your patient's body designed to.

14 And, again, that's the language that
15 Barbara McCabe from marketing had talked about in
16 that E-mail; right?

17 A. Right.

18 Q. And she says it's designed to resist wound
19 contraction or shrinkage, offer improved tissue
20 integration, result in softer, more supple tissue.

21 That's what it says; right?

22 A. Yes.

23 Q. And if you turn to the front page, the
24 very front page of this marketing document, the
25 second sentence right at the bottom says, designed

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1 for improved patient comfort. Prolift+M gives you a
2 more advanced graft so your patient gets more with
3 less.

4 Do you see that?

5 A. I do.

6 Q. And it's a little different but pretty
7 close to what she's talking about in her E-mail as
8 opposed to saying designed to, designed for.

9 Do you see that?

10 A. Yes.

11 Q. Okay. I promise I'm not going to ask you
12 a lot about this but I want to spend five or ten
13 minutes with this document that I know you were asked
14 about previously. This is Exhibit T-1333.

15 You have in front of you Exhibit T-1333,
16 which is the Johnson & Johnson Worldwide medical
17 device and diagnostics policy for investor --
18 investigator-initiated studies. It says clinical
19 studies; right?

20 A. Right.

21 Q. And we established earlier that this was
22 put into effect in 2009?

23 A. Yes.

24 Q. I just want to go through a little bit of
25 the language of it for a few moments.

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1 At the very beginning in the introduction
2 it says, this document sets forth the policy by which
3 Johnson & Johnson medical devices and diagnostics
4 affiliates worldwide will develop and implement
5 programs to provide support for clinical
6 investigator-initiated studies, which are abbreviated
7 as IISs; correct?

8 A. Correct.

9 Q. And Johnson & Johnson medical devices and
10 diagnostics affiliates worldwide would include
11 Ethicon; right?

12 A. Yes.

13 Q. In the next paragraph it talks about the
14 fact that this is establishing standards of conduct
15 to apply to those responsible for medical aspects of
16 research and development and it talks about the
17 principles that guide ethical decision-making that
18 will promote the appropriate use of our products and
19 the best interests of our patients, their families
20 and their health-care providers.

21 See that?

22 A. Yes.

23 Q. And you would agree with me that it's a
24 good thing to have a policy like this but ultimately
25 the most important thing is to adhere to the policy;

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1 right?

2 A. Correct.

3 Q. And let's talk about a little bit of what
4 they say that the aspects of this ethical
5 decision-making is.

6 And there's some bullet points. Do you
7 see those?

8 A. I do.

9 Q. It talks about the well-being of the
10 subject is first.

11 That would be the patient comes first;
12 right?

13 A. Yes.

14 Q. Credo-based values should be applied in
15 the design and conduct of studies.

16 That's referring to the Johnson & Johnson
17 credo to put the patient first; correct?

18 A. Correct.

19 Q. It is our responsibility to adhere to the
20 principles of good clinical practice. Product
21 information is relevant, accurate, fair and balanced.

22 It's talking about making sure that the
23 truth and the whole truth is being told, not just one
24 side of the story; right?

25 A. Right.

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1 Q. Cross-cultural differences are accounted
2 for. And, last, we must vigorously raise and vet
3 medical and ethical concerns; right?

4 A. Right.

5 Q. And then it says, IISs supported by the
6 Johnson & Johnson family of companies should be
7 conducted with these same rigorous scientific and
8 ethical standards.

9 And that's essentially the -- the broad
10 scope of what this policy is supposed to achieve;
11 correct?

12 A. Yes.

13 Q. If you could, turn to Page 7.

14 On Page 7 is Section 5.1.3 titled
15 "Conflict of Interests."

16 Do you see that in front of you?

17 A. Uh-huh. Yes.

18 Q. And it talks about the fact that the
19 supporting medical device and diagnostics company,
20 which in the case of studies promoted or -- or paid
21 for by Ethicon, that would be Ethicon; right?

22 A. Right.

23 Q. The supporting MD&D company will give
24 enhanced scrutiny to managing conflicts of interest
25 in clinical research.

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1 See that?

2 A. Uh-huh.

3 Q. And I --

4 A. Yes.

5 Q. And I think you would agree with me that's
6 a very important thing to do, to make sure that any
7 potential conflicts of interest are carefully
8 managed; right?

9 A. Right.

10 Q. And the reason being because if someone
11 has a conflict of interest when they're running a
12 study, that can have impacts in all different aspects
13 of how the study is designed, conducted, reported.
14 It all can be influenced by a conflict of interest,
15 potentially.

16 A. Potentially is correct.

17 Q. And in the body of the paragraph under
18 here it points out, in part, however, once an
19 individual has an ownership interest in a medical
20 device and diagnostics company product, that
21 individual will not be considered for future support
22 of investigator-initiated studies in which the safety
23 or effectiveness of that product is under
24 investigation.

25 See that?

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1 A. Yes.

2 Q. And that would exclude, for example, if
3 Dr. Ulmsten and Dr. Eriksson were to approach Ethicon
4 today and say we want to do a study and we want you
5 to help support this study, we're going to study the
6 TVT, knowing that they own a part of the company that
7 developed the device and they have an ownership
8 interest, per this policy, that could not happen.

9 A. Yeah.

10 MR. SNELL: Foundation, form.

11 THE WITNESS: I don't know that they have
12 -- so I don't know what their business relationship
13 is, but if an investigator does -- so I agree with
14 this policy.

15 MR. SLATER: Okay.

16 BY MR. SLATER:

17 Q. If, in fact, Dr. Ulmsten and Dr. Eriksson
18 have a ownership interest in the TVT --

19 A. Right.

20 Q. -- at a point when they approach the
21 company, if this policy is in effect, they can't be
22 funded through an IIS grant; right?

23 A. Right.

24 Q. Let's go now to Page 10. Page 10, there's
25 a section on publications.

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1 A. Sorry. Yeah.

2 Q. And it says, this section states the
3 minimum requirements for the review and acceptance of
4 the publication deliverables from supported IISs and
5 to the policy regarding support of publications.

6 That's just generally saying this is what
7 this covers; right?

8 A. Yes.

9 Q. The second paragraph under publications
10 says, each medical device and diagnostics company
11 will institute a process for the review and
12 acceptance of the publication deliverables with the
13 objective of confirming that the deliverables, and
14 then they have a list of things that need to be
15 confirmed, that they fulfill the contractual
16 requirements, accurately represent the findings of
17 supported IISs and, three, do not jeopardize
18 intellectual property submissions.

19 Do you see that?

20 A. I do.

21 Q. What is a publication deliverable, in
22 general terms?

23 A. Let me read this for one sec.

24 Yeah. So my -- my understanding of this
25 would be we do as of that -- the -- the establishment

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1 of this document or guideline have a policy whereby
2 when we do research, it should be published.

3 Certainly, for our own -- our own company-sponsored
4 studies, that's absolutely the case.

5 So we would not -- we would not do research
6 and then have a finding that was other than what we
7 wanted and then not publish it because that goes
8 against publication ethics or scientific publication
9 ethics.

10 Similarly, when we evaluate a -- a request
11 for an investigator-initiated study and have a
12 contract with them, the same expectation -- we
13 can't -- we can't write the publication, we can't
14 submit it, but our -- but our contract would call for
15 them to do so, so make public their findings. So
16 that would be a publication deliverable. That's my
17 understanding.

18 Q. Okay. Let me ask you one thing you said
19 earlier. I just want to break it out and understand
20 it.

21 Am I correct that, from your perspective,
22 if a study is performed by your company or your
23 company funds a study, as an ethical matter, you
24 believe the results should be published, regardless
25 of the results?

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1 A. Yes, that's part of the publication policy,
2 at least currently.

3 Q. Okay. Even before this policy was in
4 effect, from a medical and a clinical study
5 perspective, you would have said to me, yes,
6 ethically, if our company conducts a study or funds a
7 study, the results should be published, regardless of
8 whether the -- the results are favorable or
9 unfavorable to our company.

10 A. Yeah, I adhere to that philosophy.

11 Q. Let's look under the publications, halfway
12 down, it says -- there's a paragraph that starts with
13 the word "note."

14 A. Uh-huh.

15 Q. And I want to just ask you about the last
16 sentence there. It says, any review or support
17 provided by the medical device and diagnostic company
18 must in no way interfere with the investigator's
19 primary role in interpreting the study results and
20 drawing conclusions in a manner consistent with the
21 scientific method.

22 Do you see that?

23 A. Yeah. I -- I was reading from the top so
24 let me catch up to you. But yes.

25 Q. Does that, in essence, mean we can review

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1 the study results, we can review the manuscript, but
2 we should not be making any effort to either
3 implicitly or explicitly influence how the
4 investigator is interpreting the study results or to
5 influence the conclusions that the investigator is
6 drawing?

7 A. So my -- my understanding of this paragraph
8 is and our -- our contract would call for, we -- we
9 do have the right to see the information, the data,
10 we do have a right to review the -- the manuscript of
11 whatever the publication form is and we are able to
12 offer comments but we can't -- there's no -- we have
13 no final say. The -- the investigator himself or
14 herself has the final determination of what goes into
15 the manuscript but it's -- but we are able to provide
16 comment.

17 Q. In providing the comments, based on this
18 policy, would it be fair to say that the comments
19 have to be provided in a neutral way, not in a
20 coercive way, where it's being made clear to the
21 investigator, hey, this could, in fact -- this could
22 impact on our company so we'd really rather you say
23 it differently?

24 That would be inappropriate, under this
25 policy; right?

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1 MR. SNELL: Form.

2 THE WITNESS: My expectation would be that
3 the -- the company representatives that are reviewing
4 and providing comments would be adding their thoughts
5 relative to the scientific integrity of the report.

6 BY MR. SLATER:

7 Q. It would be inappropriate for those from a
8 Johnson & Johnson company to make comments as part of
9 the review that would be designed to change
10 conclusions, for example, drawn by the investigator
11 if they were concerned that that conclusion that the
12 investigator had drawn initially could be harmful to
13 Johnson & Johnson's business.

14 A. Unless our scientific interpretation of the
15 data were such that we didn't agree with the
16 conclusions, even though they were harmful, we would
17 have the ability to make comments and say we don't
18 agree with the -- the conclusions being drawn or we
19 would suggest thinking, you know, whatever.

20 Q. If your reviewers from your company were
21 to feel that there was something about the
22 interpretation that was inaccurate, objectively
23 inaccurate, it would be important to explain that as
24 part of the feedback to the investigator to say,
25 look, you know, you've said this, we think you missed

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1 this on the analysis, so if you look at it this way,
2 please consider maybe there's a different way to
3 analyze this? That type of thing you're saying would
4 be okay.

5 A. Yes.

6 Q. If the investigator drew a conclusion, for
7 example, saying, look, based on this data, you know,
8 I think that more rigorous testing should be done on
9 these types of devices, for example, would it be
10 appropriate for the reviewers to say, hey, you know,
11 we'd rather you not say that because that could
12 actually impact on our ability to get things to
13 market?

14 MR. SNELL: Form.

15 THE WITNESS: I would not expect the
16 scientists to directly link their review of the
17 publication to a commercial outcome.

18 BY MR. SLATER:

19 Q. Let's look at the last part of the
20 publications section. It says at the very bottom,
21 all material support and editorial contributions by
22 medical device and diagnostics company personnel will
23 be acknowledged in any presentation or manuscript
24 that arises from the supported research according to
25 the ICMJE uniform requirements, Reference 10.2, and

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1 the requirements of the journal to which the
2 manuscript is submitted.

3 Do you see that?

4 A. I do.

5 Q. Would one aspect of that provision be that
6 if your company not only reviewed a manuscript but
7 had editorial input as part of the review, making
8 suggestions, you should change the article in this
9 way or that way, that that should be acknowledged in
10 the article? And I'm looking where it says,
11 editorial contributions.

12 A. Right. Yeah, the policy would say, for
13 sure. I mean, the -- the manuscript should reflect
14 support, whether it's money, product or whatever, and
15 editorial contributions, I guess that would be to say
16 the company had visibility to the manuscript or
17 something like that. So I don't find anything wrong
18 with that.

19 Q. What I'm asking is this: Based on this
20 provision, if people from your company review the
21 manuscript, for example, before it was submitted to a
22 journal and had editorial input, for example, delete
23 this, change the wording of that and actually had
24 input as opposed to just reviewing it and saying,
25 okay, we've read it and didn't give any input, those

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1 editorial contributions should be recognized in the
2 article, correct, according to this provision?

3 MR. SNELL: Form.

4 THE WITNESS: Yeah. Yeah. I'm not
5 positive I understand what's meant by editorial --
6 editorial contribution. Is that what it says? Yeah,
7 editorial contributions. But I -- I think it is
8 for -- in terms of transparency, important for
9 readers to understand who had -- who contributed to
10 authorship and -- and construction of the manuscript.

11 BY MR. SLATER:

12 Q. And you would agree with me that editorial
13 input is a contribution to the ultimate final
14 product; right?

15 A. Yes.

16 Q. These -- the policies set forth in this
17 document, were these policies in effect within your
18 company as a matter of policy even though they
19 weren't documented in such a document, in an
20 unwritten form? Meaning, was it expected that your
21 company would adhere to these types of principles
22 even before it was documented in this policy?

23 MR. SNELL: Form.

24 Go ahead.

25 THE WITNESS: I don't know that -- I don't

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1 know that we had any sort of formal policy above and
2 beyond or preceding this one.

3 I think there may have been an older MD&D
4 publication policy. And in Ethicon, you know, our
5 publication policy was largely around a process by
6 which publications would be produced, reviewed and
7 approved. So I can't swear to it. I -- I think
8 there was a publication policy in place in MD&D prior
9 to this one. I think that's the case.

10 BY MR. SLATER:

11 Q. On the very first page of this it talked
12 about the genesis or the -- the foundational source
13 for these policies being things like the Johnson &
14 Johnson credo and medical and ethical --

15 A. Yeah.

16 Q. -- considerations and good clinical
17 practice, things like that.

18 A. Yep.

19 Q. The -- the specific provisions that I've
20 discussed with you --

21 A. Yeah.

22 Q. -- would you agree that even before this
23 policy was formally adopted, that those were things
24 that Johnson & Johnson medical device and diagnostics
25 company should have been doing as an ethical matter

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1 anyway?

2 A. Yeah, those are consistent, in my world or
3 in my view, with GCP, to start with.

4 (Exhibit T-1347A was marked for
5 identification.)

6 BY MR. SLATER:

7 Q. When you say GCP, you're talking about
8 good clinical practice; right?

9 A. Yes, I am.

10 Q. Okay. What I've handed you as Exhibit
11 1347 is a TVT marketing sales aid for doctors.

12 Do you see this?

13 A. I do.

14 Q. What I'd like to do now is turn to the
15 second page, and in the right-hand column -- well,
16 rephrase.

17 On the second page of this after the cover
18 the title says, long-term data and clinical
19 experience prove exceptional efficacy and safety.
20 And then it says, five years of exceptional efficacy,
21 and then on the right-hand side right under that,
22 cured/improved success rate and studies evaluating 50
23 or more patients.

24 Do you see that?

25 A. I do.

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1 Q. And it then lists the studies with rates
2 of cured or improved patients in those studies.

3 See that?

4 A. I do.

5 Q. And it includes studies by Ulmsten;
6 correct?

7 A. It does.

8 Q. And, in fact, if you look to the -- the
9 end of this document, the references, Reference 1 is
10 a study in which Ulmsten participated with Dr.
11 Nilsson and others, Reference 4 is Ulmsten, a
12 three-year followup of tension-free vaginal tape for
13 surgical treatment of female stress urinary
14 incontinence, and Number 5 is Ulmsten and other
15 authors, a multi-center study of tension-free vaginal
16 tape for surgical treatment of stress urinary
17 incontinence.

18 See those?

19 A. I do.

20 Q. And, in fact, Reference 5 is the published
21 article from the multi-center study that was
22 submitted in report form to the FDA with the 510(k);
23 correct?

24 A. I believe that's right.

25 Q. Exhibit 5 -- rephrase.

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1 Reference 5 is the study that was
2 performed -- in the internal documents it's the
3 Medscan study but -- but Ulmsten was the first listed
4 author on that, correct, the multi-center trial?

5 MR. SNELL: Form.

6 I'm sorry. I totally didn't understand
7 that question.

8 MR. SLATER: I'll ask it again. That's
9 fine. I probably was talking too quick or too low or
10 too garbled. Okay. Let me -- let me ask again.

11 BY MR. SLATER:

12 Q. Reference 5 in this document is a study in
13 which Ulmsten is the first listed author, and that is
14 the multi-center study that was conducted by Medscan.

15 A. I think that's right, yeah.

16 Q. And we've -- we've talked earlier about
17 the provisions in the Agreement between Johnson &
18 Johnson and Medscan, the -- the provisional payment,
19 et cetera.

20 A. Right.

21 Q. We've talked about that.

22 A. Right.

23 Q. Is -- I don't see anywhere in this
24 document any disclosure of that financial provision
25 and, you know, I would ask you if you see anything

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1 that would indicate that it was disclosed to doctors
2 that that study had a provision like that in it.

3 MR. SNELL: Well, form.

4 THE WITNESS: Yeah. That study what?

5 MR. SLATER: Had that provision, the
6 provision which said the \$400,000 payment will only
7 be made if there is no significant difference in the
8 adverse events as compared to Ulmsten's original
9 study.

10 There's no disclosure that such a
11 provision existed, even though that study is actually
12 cited as support for exceptional efficacy and safety.

13 MR. SNELL: Form.

14 BY MR. SLATER:

15 Q. Correct? Unless you see something that
16 I'm missing.

17 A. I mean, I have to look, because I've never
18 seen this before.

19 Q. Fair enough.

20 A. I don't -- no, I don't see a reference or a
21 notation.

22 Q. This document, this marketing aid
23 regarding the TVT, at the end of the document has
24 a -- very bottom left corner of the last page, it
25 says 2002, so that gives us some idea of the time

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1 period when it was put into effect, probably; right?

2 A. Right.

3 Q. Now, let's go, if we could, to the next
4 page, the third page of this, where it says, all the
5 tools for success.

6 Do you see that?

7 A. I do.

8 Q. The first thing it says, unique mesh with
9 exceptional clinical performance, and then it gives
10 the basis for that claim, and the first one, proven
11 biocompatibility. Composed of Prolene polypropylene
12 material used in Ethicon sutures.

13 Do you see that?

14 A. Yep. Yes.

15 Q. So one of the things doctors are being
16 told is the biocompatibility of this mesh has been
17 proven, in part, by the biocompatibility of sutures;
18 correct?

19 A. Yeah.

20 Q. And you would certainly agree with me that
21 the profile of risks with Prolene sutures is
22 different than the profile of risks with Prolene
23 mesh; correct?

24 MR. SNELL: Form.

25 THE WITNESS: Yes, the -- the risks of

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1 that -- of the TVT procedure includes the risk for
2 mesh exposure, which can't occur if you don't put a
3 mesh in.

4 BY MR. SLATER:

5 Q. In terms of the profile of risks as
6 between Prolene suture and Prolene mesh, for example,
7 in the TVT, if you just look at the mesh itself
8 versus the -- the suture, there are significant risks
9 with the mesh that don't exist with the suture, one
10 of them being erosion or exposure; correct?

11 MR. SNELL: Form.

12 THE WITNESS: Yeah.

13 BY MR. SLATER:

14 Q. Another would be contraction due to scar
15 tissue; correct?

16 A. Yes.

17 Q. Another would be the consequences of
18 either erosion or contraction, and you could list
19 those, the need for surgery to remove contracted or
20 eroding mesh; right?

21 A. Right.

22 Q. Also, pain that can be suffered as a
23 result; correct?

24 A. Correct.

25 Q. Look down, if you could. Below the second

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1 bullet point there's a -- the third thing that's --
2 rephrase.

3 Under the section that says, unique mesh
4 with exceptional clinical performance, towards the
5 bottom of that section it says, no foreign body
6 reaction after Prolene mesh implantation.

7 Do you see that?

8 A. I do.

9 Q. You know and would agree with me that
10 there is a foreign body reaction with Prolene mesh;
11 right?

12 A. Yes.

13 Q. So this statement is inaccurate, based on
14 your knowledge of the biocompatibility of Prolene
15 mesh; correct?

16 MR. SNELL: Form.

17 THE WITNESS: It's incorrect to say
18 there's no foreign body reaction for any implant.

19 BY MR. SLATER:

20 Q. If you could, turn to the second-to-last
21 page. It says that, Gynecare TVT works the way you
22 do. And the fourth bullet point there says, broad
23 application.

24 Are you with me?

25 A. I am now. Sorry. I wanted to look at

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1 the --

2 Q. No problem.

3 A. I wanted to remind myself of the date.

4 Q. It's fine. I'll start over.

5 Here on the second-to-last page of this
6 document it says about a third of the way down,
7 Gynecare TVT works the way you do. And it says,
8 broad application. May be performed under local,
9 regional or general anesthesia.

10 Do you see that?

11 A. I do.

12 Q. There's no disclosure that the efficacy
13 rate -- rephrase.

14 There's no disclosure that there is a
15 reduction in efficacy, meaning it's not as good
16 outcomes, when general anesthesia is used as opposed
17 to other local or regional anesthesia.

18 That's not disclosed; correct?

19 A. It doesn't say --

20 MR. SNELL: Form and foundation.

21 Go ahead.

22 THE WITNESS: Yeah. It doesn't say that
23 here, no.

24 BY MR. SLATER:

25 Q. And you're aware that with general

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1 anesthesia the efficacy rates drop with the TVT.

2 A. I'm not aware.

3 Q. You've never been told that?

4 A. (Witness shakes head.)

5 Q. If one of the medical affairs directors
6 who was responsible for the TV -- TVT testified that
7 with general anesthesia there is a reduction in
8 efficacy because you can't do a cough test, you
9 wouldn't argue with that, would you?

10 MR. SNELL: Form.

11 THE WITNESS: I would actually ask for the
12 data.

13 BY MR. SLATER:

14 Q. And if -- if a medical affairs director
15 testified that there was data available that showed
16 that, do you have any reason as you sit here now to
17 say, well, I know something different?

18 A. No.

19 Q. Okay. You would agree with me that if
20 your company was aware that efficacy was lower with
21 the TVT or any SUI device when general anesthesia
22 would be used, as opposed to local, that's something
23 doctors would need to be told.

24 A. If it was a well-established fact, yes.

25 Q. You would agree that's the kind of thing

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1 that could actually be very significant to a
2 physician and a patient in deciding whether to have
3 that treatment provided or how the treatment should
4 be given; correct?

5 A. It sure --

6 MR. SNELL: Form.

7 Go ahead.

8 THE WITNESS: It would be an input, sure.

9 (Exhibit T-1348A was marked for
10 identification.)

11 MR. SLATER: We're up to 1348.

12 Just so you know, I'm down to like two or
13 three exhibits so I'll probably take a break after
14 these couple more exhibits, check my notes, and then
15 other than maybe a few clean-up questions, and I
16 don't really have any notes so I'll probably -- I'll
17 probably be handing it off soon. Then Burt has about
18 a ten-hour Direct. So we're going to bed down --

19 MR. SNELL: I've got a little bit.

20 MR. SLATER: -- light a fire. Okay.

21 BY MR. SLATER:

22 Q. Exhibit 1348 is a TVT marketing document,
23 and if you look at the last page, it has a copyright
24 date of 2004.

25 A. Okay.

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1 Q. That would tell us it was probably used
2 around 2004 or so; right?

3 A. I -- yep. I would assume so.

4 Q. Okay. And right on the cover of this
5 marketing document it's titled "Only Gynecare TVT Has
6 Long-Term Results You Can See and Believe."

7 See that?

8 A. I do.

9 Q. So they're telling doctors, there are
10 long-term results that have been documented, that you
11 can believe them, you can rely on them; right?

12 A. Yes.

13 Q. Let's go to the second page. It says,
14 only Gynecare TVT has seven years of proven clinical
15 efficacy data. And right in the first bullet point
16 it says, the success of Gynecare TVT has been proven
17 in multiple studies evaluating 50 or more patients.

18 Do you see that?

19 A. I do.

20 Q. And if you look at what the citation is,
21 the references are 2 to 12, and you go to the end,
22 that includes Reference 2, which is an Ulmsten
23 article, Reference 3, which is Ulmsten, the Medscan
24 multi-center trial --

25 A. I'm not there yet so --

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1 Q. -- that we've discussed previously;
2 correct? It's the second-to-last page.

3 A. Okay. Which ones? I see --

4 Q. Two and three.

5 A. Yes.

6 Q. I see no disclosure of any financial
7 conflict of interests with regard to those studies
8 anywhere in this document. Do you?

9 A. No, I don't. Well, wait. Another page or
10 two. No, I don't.

11 Q. And if you go down to the next bullet
12 point on this second page, it talks about the fact
13 there's more clinical data than any other
14 mid-urethral sling device and then it gives certain
15 aspects of that and, again, there are citations to
16 those references, and it talks about the retention
17 rate and cites to References 2 to 6, which would
18 include the Ulmsten study, and 2 to 12 for the next
19 point about no reported urethral erosions.

20 So that -- that -- those studies by
21 Ulmsten and Medscan are to be relied on to give
22 positive claims to doctors; right?

23 A. Right.

24 Q. At the very bottom of this page it says,
25 proven in different patient types.

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1 So that's saying that the safety and
2 efficacy of the TVT has been proven in various
3 different patients and we're given some examples
4 there.

5 Do you see that?

6 A. I do.

7 Q. Advanced elderly women?

8 They're saying to doctors it's been proven
9 safe and effective for advanced elderly women; right?

10 A. Yes. Yeah.

11 Q. It says, obese women.

12 So that's telling doctors the TVT has been
13 proven safe and effective in obese women; correct?

14 A. Correct.

15 Q. And it says, women with prior
16 peri-urethral collagen injection.

17 And it's saying that women who meet that
18 standard, also, it's been proven safe and effective
19 for them; correct?

20 A. Correct.

21 Q. If you go to the -- go a couple pages
22 later, it says, only Gynecare TVT uses Prolene
23 polypropylene mesh, the same material used in Ethicon
24 sutures.

25 See that page?

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1 A. I do.

2 Q. So your company is saying to doctors in
3 this marketing document, you can rely on the fact
4 that Ethicon Prolene sutures are safe and you should
5 expect safety of this Prolene mesh just as much;
6 right?

7 A. No. I think they're just saying it's made
8 of the same material and well-established use in
9 humans.

10 Q. Let me ask the question differently, in a
11 way that actually makes some sense, hopefully.

12 Doctors are being told here that the
13 material used in the mesh for the TVT is the same
14 material used in Ethicon's sutures and they're being
15 told that's something that they can rely on as
16 contributing to the safety of this material; right?

17 A. Doesn't actually say that. It just -- I
18 mean, it only says it's made of the same material.

19 Q. The reason to say that in the marketing
20 document like this is to imply that it's a positive
21 attribute; right?

22 That's what your marketing people want to
23 do is convince doctors, hey, buy our device so,
24 presumably, they're going to say things that are
25 going to help doctors to feel comfortable with using

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1 it; right?

2 A. Yeah. I mean, I wasn't there when they put
3 it together, but it's the same material and -- and
4 physicians would have recognition for what that
5 means.

6 Q. Toward the bottom of this page it says,
7 continence occurs because Gynecare TVT mesh, and then
8 the first bullet point, reinforces the dysfunctional
9 pubourethral ligaments.

10 Do you see that?

11 A. I do.

12 Q. And I've seen somewhere -- and tell me if
13 I understand this right -- that what the TVT is, it
14 acts essentially as a ligament or in a ligamentous
15 capacity to support the urethra; is that correct?

16 MR. SNELL: Form. Form.

17 THE WITNESS: So strict definition of a
18 ligament would be bone-to-bone connective tissue
19 providing mechanical support of some sort. So I
20 don't know what you'd call -- I don't know if you can
21 call a device a ligament but --

22 BY MR. SLATER:

23 Q. The TVT is intended to function similarly
24 to a ligament; correct?

25 A. I don't know -- I don't know that I can say

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1 that with certainty.

2 Q. Have you ever seen information or
3 documentation or been involved in discussions where
4 that was recognized?

5 A. No. No.

6 Q. Okay. At the bottom of this page, the
7 page that talks about the same material being used in
8 the Prolene mesh that's used in Ethicon sutures,
9 there's a quote from Dr. Nilsson that the TVT
10 procedure seems to result in good long-term cure with
11 cure rates similar to the best traditional
12 incontinence operations.

13 Do you see that?

14 A. I do.

15 Q. Dr. Nilsson was a paid consultant to your
16 company and was paid in connection with the studies
17 performed by Dr. Nilsson; correct?

18 MR. SNELL: Form.

19 THE WITNESS: I don't know that, no.

20 MR. SNELL: Foundation. Sorry.

21 You can go ahead.

22 MR. SLATER: I'm sorry. You're objecting
23 to the foundation? You don't think Dr. Nilsson --

24 MR. SNELL: On the studies. On the
25 studies.

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1 Go ahead.

2 MR. SLATER: You don't think Dr. Nilsson
3 was paid in connection with the studies that Dr.
4 Nilsson performed? Are you saying that's an
5 inaccurate statement? Is that your objection?

6 MR. SNELL: I'm saying, foundation. Yes.
7 That has not been established, to my knowledge.

8 MR. SLATER: Well, you understand that
9 it's one thing to say that has not been established,
10 to my knowledge, but it's a different thing to say
11 that is an untrue factual assumption unless the
12 foundation is inaccurate.

13 Are you saying the latter? Are you saying
14 Dr. Nilsson was actually not paid in connection with
15 Dr. Nilsson's studies? Because that -- you could
16 make that objection if you know that to be true but
17 otherwise it's not appropriate to object to the
18 foundation of my question. And I want to make a
19 record of this because it could be important at a
20 later date.

21 MR. SNELL: You know, I might not be the
22 best person to ask for that. How about I change it
23 to it assumes facts not yet into evidence?

24 MR. SLATER: I would have the same
25 response so --

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1 MR. SNELL: Well, that's where I'm at.

2 MR. SLATER: So at the time that that
3 objection is argued that -- that will be clear, that
4 the objection was made without actually knowing
5 whether or not my statement was accurate but there's
6 no reason for you to say it isn't. Okay.

7 Let's go now --

8 (Exhibit T-1349A was marked for
9 identification.)

10 MR. SNELL: I thought Axel Arnaud
11 testified on that, in line with my objection.
12 Perhaps I'm wrong or perhaps he'll be -- he'll be
13 deposed and he'll tell you that soon enough.

14 MR. SLATER: Are you offering Axel Arnaud
15 for more deposition testimony? He will not be happy.

16 THE WITNESS: I'll hear about it.

17 MR. SNELL: I love Axel.

18 MR. SLATER: If you guys have anyone
19 listening, your phone is going to start ringing.
20 Kristy is going to be calling you up saying, hey.

21 Okay.

22 MR. SNELL: 1349?

23 MR. SLATER: Yes.

24 I just want to get all the Snapple off my
25 copy.

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1 BY MR. SLATER:

2 Q. Exhibit 13 -- I'm sorry.

3 Exhibit 1349 is a TVT marketing document
4 and it actually addresses the TVT, the TVT-O and
5 TVT-Secur, and it has a copyright date on the
6 second-to-last page, it looks like 2009.

7 A. Where?

8 Q. All the way to the bottom right of all
9 that really, really large print that you're looking
10 at.

11 A. Yes, it does look like 2009. It wasn't
12 immediately obvious.

13 Q. Okay. This document, this marketing
14 document, which appears to have a date of 2009, says,
15 make data and safety your choice. Demand the most
16 proven technology when selecting a mid-urethral
17 sling.

18 That's the title of this marketing
19 document for doctors; correct?

20 A. Correct.

21 Q. The first thing I'd like to do is turn to
22 the third page. It says, proprietary mesh, and
23 points out that not all meshes are created equal, et
24 cetera, and then there's a quote from Dr. Nilsson on
25 the left-hand side kind of angled along.

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1 Do you see that?

2 A. Yeah.

3 Q. And Dr. Nilsson's quote says, you cannot
4 transfer results from one procedure with a certain
5 design and material to another one that looks alike
6 but has some differences.

7 Do you see that statement?

8 A. I do.

9 Q. Do you agree with that statement?

10 A. Yeah, broadly.

11 Q. In essence, if you have a procedure that
12 is similar to another procedure but there are
13 differences, you can't just transfer the results from
14 one and say, well, that's what you can expect with
15 the other.

16 A. Yeah. Without understanding the nature and
17 magnitude of the differences and, you know, using
18 your -- your knowledge base to say does this really
19 matter or doesn't it.

20 Q. As a general matter, the results with one
21 procedure with a certain design will not necessarily
22 transfer to another procedure with some differences;
23 correct?

24 MR. SNELL: Form.

25 THE WITNESS: Well, not necessarily.

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1 Right.

2 BY MR. SLATER:

3 Q. And I'll give you a concrete example. For
4 example, the TVT-Secur, one could not say that you
5 could look at the results with the TVT or the TVT-O
6 and expect the same results because there are some
7 significant differences between and among those
8 devices, the Secur versus the O and the TVT; correct?

9 A. Yeah, you would want to understand, okay,
10 what -- what's the -- what's the potential impact of
11 these differences in terms of performance.

12 Q. You wouldn't want to say to doctors that
13 they can expect a certain level of safety and
14 efficacy with the TVT-Secur based on the data with
15 the TVT or the TVT-O because there are some
16 significant differences to preclude you from saying
17 one will predict the other; correct?

18 MR. SNELL: Form.

19 THE WITNESS: Yeah. Not the data in its
20 entirety, so you can't just sort of transfer all over
21 necessarily.

22 BY MR. SLATER:

23 Q. If you could, turn to the second-to-last
24 page. It has a review of published clinical data and
25 RCTs. And it says with regard to the Gynecare

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1 TVT-Secur, longer followup of one year as compared to
2 another manufacturer's similar device with a 94
3 percent objective success rate.

4 Do you see that?

5 A. We're talking about Secur. Okay. I
6 just -- I just now got there. So let me just look at
7 it.

8 MR. SNELL: Can you read that back?
9 Because I thought you added something in there, Adam.

10 MR. SLATER: I'll ask it again.

11 BY MR. SLATER:

12 Q. On the second-to-last page of this
13 marketing document from 2009 that says, make data and
14 safety your choice, there's a description of a study
15 with the TVT-Secur.

16 Do you see that?

17 A. Yes.

18 Q. And it says that -- with the TVT-Secur
19 that with one-year followup there was a 94 percent
20 objective success rate.

21 A. I see that.

22 Q. Okay. From your perspective, did your
23 company ever obtain enough data to be able to say to
24 doctors across the board, you can expect a 94 percent
25 objective success rate in terms of efficacy with the

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1 TVT-Secur?

2 A. I'm not familiar enough with the
3 information to know what they based it on, and I
4 certainly can't read the reference with this font.

5 Q. In -- in order to be fair and balanced in
6 presenting to doctors what they can expect to occur
7 with the TVT-Secur, your company would have to tell
8 what the positive results were that were known to
9 your company as well as negative results that were
10 known to your company so doctors would know both
11 sides of the story; right?

12 MR. SNELL: Form.

13 THE WITNESS: I think -- I think there --
14 the obligation would be to be fair and balanced in
15 what you present.

16 BY MR. SLATER:

17 Q. To the extent that your company presents
18 data or has presented data with the TVT-Secur saying
19 you can expect a certain level of efficacy of success
20 with the TVT-Secur in curing stress urinary
21 incontinence, to the extent your company knew that
22 there were doctors who were not just isolated doctors
23 but doctors around the world who were reporting
24 variable efficacy with very low rates, in many cases
25 under 50 percent, you would need to tell that side of

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1 the story as well to be fair and balanced; right?

2 MR. SNELL: Form and foundation.

3 THE WITNESS: I think you would need to
4 understand what the information received meant, you
5 know, what are you seeing, and as a part of a
6 promotional piece to be fair and balanced in what you
7 describe.

8 BY MR. SLATER:

9 Q. It's not for --

10 A. I don't --

11 Q. I'm sorry. I didn't mean to --

12 A. Depends on a level-of-evidence kind of
13 thing.

14 Q. It's not for your company to say, okay,
15 well, we have this good data here that has good --
16 this study came out with good results and we have
17 these other reports to our company of people that we
18 think are very good surgeons getting very different,
19 very poor efficacy, it's not for your company to say,
20 well, but we -- we can discount that and to come up
21 with a reason to say we don't need to tell anybody
22 that. It's not for your company to do that. It's
23 your company's obligation to give that information to
24 doctors in the community and let them decide the
25 significance; correct?

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1 MR. SNELL: Form.

2 THE WITNESS: I would agree to that as
3 long -- as long as the data regarding less effective
4 performance was understood well enough to say this --
5 this is informative to the physicians.

6 BY MR. SLATER:

7 Q. With regard to the TVT-Secur, the data
8 that your company was receiving regarding variable
9 efficacy and low levels of efficacy for some doctors
10 that your company had great respect for was taken so
11 seriously that Axel Arnaud was actually charged with
12 preparing what he's referred to as a, quote, unquote,
13 cookbook to give more specific information to
14 surgeons to try to get more consistent efficacy.

15 That would be a signal that your company
16 believed those reports of variable efficacy were
17 important enough to take concrete action; right?

18 A. Yeah, to -- to understand root cause and
19 correct it.

20 Q. And in that case, that variable efficacy
21 should be presented to physicians out in the
22 community or -- this is being marketed to; correct?

23 A. Or -- so, you know, your obligation is to
24 fair -- in a fair and balanced manner inform the
25 physicians with respect to the performance of the

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1 product.

2 And, again, if you had some -- some cites
3 or some anecdotal information that there was less
4 positive performance and you undertake a mitigation
5 activity and say, you know what, they weren't using
6 it properly, then you have to say, all right, what's
7 your -- what's -- what's the right thing to do?
8 We've got to make sure everybody is using it
9 properly. I think -- I believe that's what was
10 occurring.

11 Q. The most important thing would be -- well,
12 rephrase.

13 Let me ask you this: A doctor is given
14 information by a sales representative or through your
15 company about the TVT-Secur, here's what you can
16 expect from a safety perspective, here's what you can
17 expect from an efficacy perspective, and the doctor
18 is not told anything about the reports of variable
19 efficacy that were coming in to your company that led
20 to Axel Arnaud being charged with creating the
21 cookbook and the doctor has no knowledge of that at
22 all. That doctor has not been given a fair and
23 balanced presentation; correct?

24 MR. SNELL: Form. Hypothetical.

25 THE WITNESS: Again, I -- I -- I think

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1 that's true. If -- if the -- and I don't know what
2 occurred then, but that's true if you have enough --
3 what would be the word? If you have enough faith
4 in -- in the less than ideal or the -- not faith in
5 the data, in the -- in the -- in the less-than-ideal
6 outcomes that it actually reflects performance of the
7 product in the field, then that has to be part of a
8 fair-and-balanced statement.

9 BY MR. SLATER:

10 Q. And in this case your company --

11 A. Yeah.

12 Q. -- felt that that data was reliable enough
13 that your company took concrete -- concrete internal
14 action in response; right?

15 A. I don't know the details behind what all
16 occurred then. I wasn't -- that wasn't visible to
17 me. But clearly, clearly, if we -- you know, the
18 usual reaction would be, if we have reports from --
19 anecdotal reports from the field about
20 underperforming centers or doctors or whatever, we
21 would want to try to help and understand what's
22 different and try to correct that. So yeah, they
23 took it seriously.

24 Q. And when it's taken seriously like that,
25 it needs to be communicated to doctors who the

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1 product is being marketed to; right?

2 MR. SNELL: Form.

3 THE WITNESS: Yeah. Well, if you -- if
4 you have the knowledge now in your -- in your
5 possession to say we know what's going on and we know
6 what happened and here's how to mitigate it,
7 absolutely, we need to tell them how to do so.

8 BY MR. SLATER:

9 Q. Well, even if your company didn't feel
10 like it had the knowledge as to why it's happening or
11 how to mitigate it, you still need to tell doctors in
12 the field who are considering using the device, hey,
13 we have this issue, in that case, we don't -- we
14 can't even explain why it's happening, you just need
15 to know this issue is out there; right?

16 A. Yeah. If you don't know what's going on, I
17 think you're even more compelled.

18 Q. Okay.

19 (Exhibit T-1350A was marked for
20 identification.)

21 MR. SLATER: I'm sorry. I overestimate my
22 reach.

23 THE WITNESS: Whoops. I have it.

24 MR. SLATER: I got a lot of going over the
25 back fouls in basketball. My problem.

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1 MR. SNELL: 1350?

2 MR. SLATER: 1350.

3 And when you Redirect, you expect to go
4 through all 1,350 exhibits; right? I just want to
5 plan whether I'm getting back home on Monday or
6 Tuesday.

7 MR. SNELL: No, I'm not going through all
8 of them.

9 MR. SLATER: Okay.

10 BY MR. SLATER:

11 Q. Exhibit 1350 is a sales aid that has a
12 copyright date of 2010.

13 Do you see that?

14 A. I do. Well, actually, I don't.
15 Now I do.

16 Q. The title of it is, dependability,
17 Gynecare TVT family of products, tension-free support
18 for incontinence.

19 Do you see that?

20 A. Uh-huh. Yes.

21 Q. And this apparently pertains to all three
22 of your primary SUI devices, the TVT, the TVT-O and
23 the TVT-Secur, and they're pictured right across the
24 top of the front page; right?

25 A. Right.

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1 Q. And the first section talks about it being
2 the first and most widely implanted SUI mesh and then
3 there are some bullet points talking about that.

4 Do you see that?

5 A. I do, yes.

6 Q. The third bullet point says, in a clinical
7 study at an average of 11.5 years of followup not a
8 single case of tape erosion, tissue reactions or
9 other adverse effects of the tape were found.

10 Do you see that?

11 A. Yes.

12 Q. And if you look at the reference, that's a
13 reference to Nilsson's study, and at that point it
14 was the 11-year prospective followup of the
15 tension-free vaginal tape procedure for treatment of
16 stress urinary incontinence.

17 Do you see that?

18 A. Not yet. Oh, I was looking at the wrong
19 one.

20 Yes.

21 Q. Now, are you aware that the study by Dr.
22 Nilsson that has been reported all the way up to
23 recently 17 years actually did not utilize the TVT as
24 your company marketed it?

25 MR. SNELL: Form, foundation.

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1 MR. SLATER: I'm sorry. What's the
2 objection to that?

3 MR. SNELL: That's not a true statement.

4 MR. SLATER: Is it your position, Counsel,
5 that --

6 MR. SNELL: Yes, it is my position that --

7 MR. SLATER: You don't have to get angry.
8 I have to make a record.

9 MR. SNELL: It's the same -- I'm about to
10 tell you my position. It's the same --

11 MR. SLATER: Why are you getting angry?

12 MR. SNELL: It's the same TVT. It's the
13 same TVT mesh, sheath --

14 MR. SLATER: I'm going to make it very
15 clear.

16 MR. SNELL: -- needle.

17 MR. SLATER: Okay. Don't -- don't --
18 we're all really having a nice time here. You don't
19 have to get annoyed. Come on. It's Christmastime.

20 I just want to understand, Counsel, are
21 you saying that the device and procedure used by
22 Nilsson is the TVT marketed by Ethicon?

23 MR. SNELL: Yes, it's the device marketed
24 by Ethicon.

25 MR. SLATER: Okay. And, Counsel, you're

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1 aware the study actually began before Ethicon even
2 sought regulatory approval for the TVT, thus, the TVT
3 was not even being marketed yet; correct?

4 MR. SNELL: I'm not the one under
5 examination here.

6 MR. SLATER: That's fine.

7 MR. SNELL: I know that study says it uses
8 the same Prolene and TVT as used, currently marketed
9 today.

10 MR. SLATER: Okay.

11 MR. SNELL: And it describes a device
12 that's just like the one used today.

13 BY MR. SLATER:

14 Q. Dr. Nilsson -- well, rephrase.

15 There is no statement of any conflict of
16 interest with Dr. Nilsson in this document; correct?

17 A. I don't see one.

18 Q. According to this statement in this
19 marketing document from your company, Dr. Nilsson's
20 study proved that at an average of 11 and a half
21 years of followup among whatever number of patients
22 were in that study there was not one case of a tape
23 erosion, meaning not one case of TVT mesh eroding
24 anywhere, whether within tissue or through the
25 vagina.

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1 That's saying that it never happened;
2 correct?

3 MR. SNELL: Form. Form.

4 THE WITNESS: That's how I read it.

5 BY MR. SLATER:

6 Q. Knowing what you know about the TVT, do
7 you think that it is reasonable to expect that in a
8 study of more than just a few patients that over the
9 course of 11 and a half years not one patient would
10 have any sort of an erosion of mesh?

11 A. Obviously depends on the -- the number of
12 patients, but if you had a small enough number of
13 patients and they didn't have any erosions in the
14 first year or two, it's reasonable of me -- for me to
15 think that it could go on out to 11 years and not
16 have any appear after that.

17 Q. If it was more than 50 patients, do you
18 think it's reasonable to expect that none of them
19 would have any type of an erosion or an exposure at
20 all?

21 A. I'd want to sit down with a statistician
22 and say, what -- what is the known rate and what are
23 the relative probabilities?

24 Q. You'd also --

25 A. 50 is a small number.

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1 Q. I'm sorry. You'd also want to know, how
2 did you define an erosion; right?

3 A. Yes, I would. Yeah.

4 Q. One of the very important things in a
5 study like this is what were the investigators
6 defining the adverse event as because you could
7 create a definition so narrow that you could
8 essentially exclude what other people would generally
9 consider to be that adverse event; correct?

10 A. Yeah. So if you're -- if you -- if you're
11 reading a study, you would want to know exactly what
12 they're talking about, so a definition regarding
13 what -- what -- what counted as a yes or no for an
14 adverse event would be informative and important.

15 Q. This statement by your company also --
16 rephrase.

17 This statement by your company about the
18 Nilsson clinical study says that in an average of 11
19 and a half years of followup not only was there not a
20 single case of an erosion, there was -- there was not
21 a single case of a tissue reaction or other adverse
22 effects of the tape.

23 Do you see that?

24 A. I do.

25 Q. Now, you would certainly agree with me,

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1 knowing what you know, by definition, there was a
2 foreign body reaction so there has to be a tissue
3 reaction with each patient; correct?

4 A. Yeah, there would be -- there would be a
5 tissue reaction or a histologic reaction to any
6 implant.

7 Q. There would also be some level of fibrosis
8 forming at and around the mesh; right?

9 A. Right.

10 Q. So there's no way for this to be a
11 truthful statement because you can't truthfully say
12 that a doctor -- well, rephrase.

13 You would agree with me that your company
14 could not truthfully say that with a TVT over the
15 course of 11 and a half years you should not expect
16 any tissue reaction or any adverse effect of the
17 mesh.

18 You would agree with me; right?

19 MR. SNELL: Form.

20 Go ahead.

21 THE WITNESS: Literally, yes.

22 MR. SLATER: Let's take a break.

23 VIDEO OPERATOR: The time is now 2:57.

24 This is the end of Disk Number 3.

25 We're going off the record.

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1 (Recess, 2:57-3:37 p.m.)

2 VIDEO OPERATOR: The time is now 3:37.

3 This is the beginning of Disk Number 4.

4 We are back on the record.

5 BY MR. SLATER:

6 Q. Doctor, looking at Exhibit 1350 still --

7 A. Okay.

8 Q. -- in this bullet point that says there
9 was not a single case of tape erosion if within the
10 article itself it said there were no tape rejections
11 or no tape material rejections, would you equate that
12 to no tape erosions?

13 A. I have to read it in the whole context of
14 the article, I think, to understand what -- you know,
15 how one equated to the other.

16 Q. If there was no discussion -- well,
17 rephrase.

18 Just in the abstract, would you equate a
19 rejection of a TVT to an erosion of a TVT?

20 MR. SNELL: Form.

21 Go ahead.

22 THE WITNESS: I don't think you could do
23 it with the abstract. I would want to read and say
24 what -- what are they implying or what are they
25 actually describing?

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1 BY MR. SLATER:

2 Q. This is what I want to ask you: In terms
3 of your own vocabulary, you would not equate a tape
4 rejection and a tape erosion in all instances?

5 A. No, I wouldn't.

6 Q. We've talked about within various TVT
7 marketing documents citations to data from Nilsson
8 and from Ulmsten; correct?

9 A. Correct.

10 Q. If a particular study, for example, by Dr.
11 Nilsson were cited with regard to efficacy --
12 efficacy data and each of the patients was treated
13 under local anesthesia with a cough test, would you
14 agree that would be important information to provide
15 context to the efficacy data so doctors would
16 understand that that's how the procedure was
17 performed --

18 MR. SNELL: Form.

19 BY MR. SLATER:

20 Q. -- in order to get those numbers?

21 MR. SNELL: Form.

22 Go ahead. Foundation.

23 THE WITNESS: No. I think -- I think
24 the -- if the citation -- I mean, if it's cited and
25 the doctor -- if I was -- if I was reading as a

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1 physician, I would want to know how was this done and
2 how they get those results, I would -- I would go
3 look at that and -- now, I don't think in a sales
4 piece you're going to be encyclopedic and describe
5 how every procedure is done in 20 references or
6 whatever.

7 BY MR. SLATER:

8 Q. If your company knew that, for example,
9 the efficacy data for -- from Nilsson were achieved
10 with local anesthesia and a cough test with all
11 patients and your company knew that the cough test is
12 not stated to be mandatory in the TVT, it's just
13 stated as optional, so you know some doctors will not
14 utilize the cough test, under that circumstance,
15 isn't it important to tell doctors, look, we're
16 giving you this data but this data may not translate
17 to all ways of doing the procedure so don't -- if
18 you're not somebody who's using a cough test and
19 local anesthesia, you can't necessarily expect this
20 efficacy with your patients?

21 A. Yeah. I would expect --

22 MR. SNELL: Form.

23 Go ahead, Doctor.

24 THE WITNESS: I would expect the surgeon
25 receiving the information to -- to understand from

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1 their own experience what -- what the implications
2 are of one technique versus another.

3 BY MR. SLATER:

4 Q. Well, let's talk about a doctor who is
5 adopting the TVT --

6 A. Uh-huh.

7 Q. -- and doesn't have a large body of
8 experience with it so they're relying on what your
9 company is telling them they should expect and
10 doesn't have time to go and read all the articles and
11 trusts that your company cites the articles in a fair
12 and balanced way. That doctor would be at a
13 disadvantage if the doctor doesn't know, well, the
14 efficacy data we're giving you is only obtained when
15 the procedure is performed in a particular way;
16 correct?

17 A. So I would --

18 MR. SNELL: Object to form, foundation.
19 Go ahead.

20 THE WITNESS: Yeah, I would expect that
21 that surgeon from a sales aid wouldn't -- wouldn't
22 make their determination about how they're going to
23 do their procedures but would, rather, draw on
24 whatever training they obtained and -- and -- and
25 then their own experience about which way to go.

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1 BY MR. SLATER:

2 Q. If your company knew and had solid data to
3 prove that efficacy is materially better with the TVT
4 when a cough test is used and local anesthesia is
5 used, that is something that your company should tell
6 doctors right in the IFU; correct?

7 MR. SNELL: Form.

8 THE WITNESS: Well, again, surgeons don't
9 learn their -- their procedures right from the IFU
10 and -- and between prof. ed. and proctoring and --
11 and sales training, even. They have other ways to --
12 to understand what -- what particular methods are
13 available and what the outcomes are.

14 MR. SLATER: Move to strike.

15 BY MR. SLATER:

16 Q. Here's my question: If your company had
17 evidence your company deemed reliable and persuasive
18 that efficacy with the TVT is superior in a material
19 way and to a -- to a material extent when local
20 anesthesia and a cough test is used, when your
21 company described the procedure in the IFU, it would
22 be incumbent on your company to tell doctors that
23 they can expect better results if they use the local
24 anesthesia and the cough test; right?

25 MR. SNELL: Form and foundation.

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1 THE WITNESS: I -- I -- you know, within
2 the IFU I would -- I would think that would depend on
3 the -- the magnitude of the evidence, the reliability
4 of the evidence and, you know, sort of the level of
5 evidence. But not having that in my head right now,
6 it's hard for me to judge.

7 BY MR. SLATER:

8 Q. If the evidence was of a magnitude where
9 your medical affairs people that work for you deemed,
10 yes, we acknowledge that there is a material
11 difference in efficacy and it's better, to a material
12 extent, when you use local anesthesia and a cough
13 test, that information should be provided in the IFU
14 when doctors are told in the IFU this is how to do
15 the procedure; right?

16 MR. SNELL: Form.

17 THE WITNESS: Again, it's only -- it's
18 only one of the places they learn how to do it and
19 it's hard to tell whether it goes in the IFU, sales
20 training, prof. ed. and so forth. But it's --
21 it's -- again, depending on the level of evidence and
22 the magnitude of the difference, the options ought to
23 be made available and surgeons and patients would
24 make the decision about do I want to have this under
25 local or do I want to have it under regional --

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1 MR. SLATER: Move to strike.

2 THE WITNESS: -- or others.

3 MR. SLATER: Move to strike.

4 BY MR. SLATER:

5 Q. If your medical affairs people, the people
6 working for you, knew that the results are materially
7 better in terms of efficacy with local anesthesia and
8 a cough test with the TVT, that information should be
9 provided in the IFU not only to make sure that the
10 doctor knows that but so that the doctor can also
11 tell the patient that as part of the consenting
12 discussion so the doctor and the patient in deciding
13 how the procedure is going to be performed understand
14 the alternatives and what the company, your company,
15 knows are the likely outcomes; right?

16 MR. SNELL: Form and foundation.

17 THE WITNESS: I don't see how that's
18 different than the last time I answered the question.
19 It's not any different than the last one I answered.

20 BY MR. SLATER:

21 Q. Is the answer to that question yes?

22 MR. SNELL: Form and foundation.

23 THE WITNESS: No. My answer was there are
24 a variety of ways in which we train our physicians
25 and the IFU is never encyclopedic, and I would have

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1 to have -- I would have to make a judgment call, does
2 it belong in the IFU, sales training or just where,
3 I -- I personally would need more information about
4 the magnitude and the reliability of that.

5 BY MR. SLATER:

6 Q. What would the magnitude and reliability
7 of your company's knowledge that local anesthesia and
8 a cough test has a material impact on efficacy, what
9 would that have to rise to for you to say, yes,
10 include that in the IFU?

11 A. I don't know how to quantitate that.
12 That's a judgment call when you have all the
13 information in front of you.

14 Q. If the medical affairs people in your
15 company deemed the data sufficient to say, we are
16 convinced that across the board if you use local
17 anesthesia and a cough test, to a material extent,
18 the efficacy results are better, if your medical
19 affairs directors that worked for you affirmatively
20 could make that statement, then that should be
21 disclosed in the IFU; correct?

22 MR. SNELL: Form and foundation.

23 THE WITNESS: How did you start that
24 sentence? I'm just being careful about -- you
25 started it with -- yeah.

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1 MR. SLATER: Could you read it back,
2 please.

3 (The court reporter read the requested
4 portion of the record.)

5 THE WITNESS: I think it should be part of
6 the training of the surgeons, and the IFU is one
7 place that could occur.

8 BY MR. SLATER:

9 Q. Well, the one thing that you know that the
10 surgeon is going to see is the IFU. You have no idea
11 whether and no way to confirm a doctor is going to
12 take your training at all; right?

13 MR. SNELL: Well, form, foundation.

14 Go ahead.

15 BY MR. SLATER:

16 Q. I'll ask the question again. Your
17 company -- well, rephrase.

18 You understand the IFU is the primary
19 source of material information about safety and
20 efficacy; right?

21 MR. SNELL: Foundation.

22 THE WITNESS: For a surgeon in practice?

23 BY MR. SLATER:

24 Q. In terms of regulatory and medical
25 affairs' understanding of what that document's role

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1 is for a medical device company, the IFU is the
2 primary document; right?

3 MR. SNELL: Foundation and form.

4 MR. SLATER: I'm sorry. What -- what is
5 your objection? Are you saying the IFU is not the
6 primary --

7 MR. SNELL: Yes. I'm saying --

8 MR. SLATER: -- regulatory document?

9 MR. SNELL: Yes. I'm saying there is no
10 foundation on that. You're throwing that out there
11 like there's foundation on it.

12 MR. SLATER: What are you saying is wrong
13 about it?

14 MR. SNELL: That the IFU is the primary
15 one?

16 MR. SLATER: You don't know how many
17 witnesses from your company have testified --

18 MR. SNELL: Do you know how doctors --

19 MR. SLATER: I'm sorry.

20 MR. SNELL: -- testify they don't even
21 read the IFU?

22 MR. SLATER: Listen to me. I have been
23 very, very cordial to you. Between --

24 MR. SNELL: I have been cordial to you,
25 Adam.

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1 MR. SLATER: No, you're not. You're
2 raising your voice.

3 MR. SNELL: No, I'm not.

4 MR. SLATER: Listen to me. You're raising
5 your voice, you're interrupting me.

6 MR. SNELL: You're asking me questions.
7 I'm telling -- answering you.

8 MR. SLATER: Yes. You know what? I'll
9 tell you what I'm doing, Burt. You're making
10 ridiculous objections about foundation when you don't
11 even know the testimony that's been taken in this
12 case, apparently. You have multiple --

13 MR. SNELL: I --

14 MR. SLATER: Just listen. There are
15 multiple witnesses in this case who have testified
16 that the IFU is the primary regulatory document with
17 regard to any medical device. If you dispute that,
18 then you should go talk to a judge about your pro hac
19 admission in this litigation.

20 MR. SNELL: Guess what, Adam? Your
21 question went beyond the regulatory facts --

22 MR. SLATER: And medical affairs.

23 MR. SNELL: -- and went into medical
24 affairs.

25 MR. SLATER: They know that too. They've

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1 all admitted it also.

2 MR. SNELL: No, they haven't. Now
3 you're -- now you're making statements --

4 MR. SLATER: You think so?

5 MR. SNELL: -- beyond that. Yes.

6 MR. SLATER: You think so?

7 MR. SNELL: Yes.

8 MR. SLATER: I've taken every deposition
9 and I'm telling you yes. But you know what? Keep
10 your frivolous objection.

11 MR. SNELL: It's not a frivolous
12 objection.

13 MR. SLATER: You know what? Doctor, I
14 apologize to you. This deposition is going to go a
15 lot longer now.

16 And I'll tell you another thing --

17 MR. SNELL: Why don't you just --

18 MR. SLATER: -- when your counsel starts
19 asking you questions, I'm going to follow up on every
20 one of them, and you're going to regret you did it
21 like every time you do it.

22 Now you set me off. You shouldn't have
23 done it. Now we're going to get serious. I'm going
24 to continue.

25 MR. SNELL: That's fine. I wasn't trying

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1 to stop you.

2 MR. SLATER: I'm sorry. I'm talking to
3 your witness.

4 MR. SNELL: You asked me a question, I
5 answered you.

6 MR. SLATER: I'm sorry. I'm not talking
7 to you right now.

8 MR. SNELL: All right. Go ahead.

9 BY MR. SLATER:

10 Q. Doctor, the only -- rephrase.

11 Do you understand the purpose of the IFU?

12 A. Yes. It's a regulatory -- it's a
13 regulatory document that's placed in the product
14 packaging to provide users with a description of the
15 product and its use.

16 Q. Take a look at Exhibit 1350, the one
17 that's right in front of you.

18 See on the bottom left corner, the front
19 page, it says, for complete indications,
20 contraindications, warnings, precautions and adverse
21 reactions please reference the full package insert.

22 Do you see that?

23 A. I do.

24 Q. The package insert is the IFU; right?

25 A. It is.

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1 Q. And the purpose of the IFU is to provide a
2 surgeon, for example -- well, rephrase.

3 And the purpose of the IFU is to provide a
4 complete statement of what the company knows with
5 regard to the indications, the contraindications, the
6 warnings, the precautions and the adverse reactions
7 for the device; correct?

8 A. Correct.

9 Q. Therefore, if your company, your medical
10 affairs people, knew that using a cough test and
11 local anesthesia would have a material impact on the
12 efficacy that could be expected with the use of the
13 TVT, that needed to be warned about in the IFU;
14 correct?

15 MR. SNELL: Form.

16 Go ahead.

17 THE WITNESS: It -- it needed to be --
18 that information should be provided as training for
19 the surgeon and an IFU is a place where it could go,
20 yeah.

21 MR. SLATER: Move to strike.

22 BY MR. SLATER:

23 Q. The answer to my question is, if what I
24 just asked you is accurate, that information needs to
25 be in the IFU; correct?

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1 MR. SNELL: Form. Asked and answered
2 three times.

3 THE WITNESS: I still have the same
4 answer, that if it's materially to the -- to the
5 surgeon's use, then they need to be informed and
6 trained on it.

7 BY MR. SLATER:

8 Q. You don't know if a doctor is going to do
9 your training; right?

10 A. I don't know.

11 Q. You know that if a doctor opens the
12 package, the IFU is going to be there; right?

13 A. Yes.

14 Q. If your company knew that the use of local
15 anesthesia and a cough test would have a material
16 impact on the efficacy with the TVT, it would not be
17 acceptable to omit that information from the IFU;
18 correct?

19 MR. SNELL: Form.

20 THE WITNESS: If -- so I keep saying the
21 same thing: If the information is reliable and
22 accepted and it -- and it -- the magnitude of what --
23 of the -- the difference in performance that we're
24 talking about, the IFU is a very logical place to put
25 it.

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1 BY MR. SLATER:

2 Q. In fact, under your understanding of
3 what's required and, for example, what it says right
4 here on this marketing document, to give a complete
5 statement of the warnings, precautions, et cetera,
6 that information would need to be in the IFU;
7 correct?

8 MR. SNELL: Form.

9 THE WITNESS: Again, very logical place to
10 put it, yes.

11 BY MR. SLATER:

12 Q. Based on your understanding of how the
13 regulatory world impact -- rephrase.

14 Based on your understanding of the
15 regulatory framework, it would be required that that
16 information would be in the IFU; correct?

17 MR. SNELL: Form.

18 THE WITNESS: I -- you know, I would -- I
19 would consult with the regulatory professional and
20 say, here's what we know, where does this belong,
21 from a regulatory standpoint.

22 BY MR. SLATER:

23 Q. And based on your understanding of what
24 belongs in an IFU, if the information reached that
25 magnitude and your company knew what we just

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1 discussed, it should be in the IFU; right?

2 MR. SNELL: Form.

3 THE WITNESS: That still is -- that's
4 still the same question, it's still the same answer,
5 that -- that I believe the company has the duty to
6 inform and -- and then the team should sit with the
7 regulatory professionals or whoever and say, hey,
8 where does this go, how do we teach it, what's the
9 most reliable way to get this into the user's
10 knowledge base?

11 BY MR. SLATER:

12 Q. Based upon your understanding of how
13 information gets to doctors through medical device
14 information from your company, if information is
15 deemed critical, one place it needs to be is in the
16 IFU; right?

17 A. Yeah. Yes.

18 Q. And you would agree with me, if your
19 company knew that the efficacy with the TVT was
20 materially better if one used local anesthesia and a
21 cough test, that would be critical information to
22 tell a surgeon; right?

23 MR. SNELL: Form.

24 THE WITNESS: Again, it would come back to
25 magnitude and -- and level of evidence --

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1 BY MR. SLATER:

2 Q. And if it --

3 A. -- but they're certainly --

4 Q. And if it was something your medical
5 affairs people were convinced was accurate, it would
6 be critical to put that information in the IFU;
7 right?

8 A. I can certainly think that that could be,
9 yes.

10 Q. If that information was understood by your
11 medical affairs people to reach that level of
12 magnitude, that would be deemed critical information
13 to get to a surgeon; correct?

14 MR. SNELL: Form.

15 THE WITNESS: So if it was a critical
16 difference and the magnitude or the reliability of
17 information and so forth level of evidence was
18 sufficient, then it's -- it would be important for
19 the surgeons to have that information, yes.

20 BY MR. SLATER:

21 Q. Would be critical; right?

22 A. You can call it critical, yeah.

23 Q. If there was -- rephrase.

24 If your medical affairs people that worked
25 for you were aware of somewhere on the order of a 10

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1 to 15 percent difference in efficacy with local
2 anesthesia and a cough test, meaning if you don't use
3 those two steps, you have a 10 to 15 percent worse
4 rate of efficacy?

5 A. Yeah. I think you've got level 1-A
6 evidence that that -- that that existed but that's a
7 substantial difference that should be -- that
8 physicians should be informed, yes.

9 Q. In the IFU; correct?

10 A. It's a good place to put it, yeah.

11 Q. The right place to put it; right?

12 A. It's --

13 MR. SNELL: Form.

14 That's a question you've asked him 20
15 times.

16 MR. SLATER: I don't really care,
17 honestly, what you have to say.

18 MR. SNELL: In fact, you just want him to
19 change his answer.

20 MR. SLATER: No. What I'm doing is --

21 MR. SNELL: It's been asked and answered
22 10 times.

23 MR. SLATER: Burt, let me tell you what's
24 happening here.

25 MR. SNELL: Go ahead. I'm just making a

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1 record.

2 MR. SLATER: I'm actually going to be
3 involved in the trial, not sitting in the fourth row,
4 so can I continue?

5 MR. SNELL: Go ahead. I'm just making my
6 record. Asked and answered for about the tenth time.

7 MR. SLATER: That's great.

8 BY MR. SLATER:

9 Q. Under those circumstances, that
10 information must be put in the IFU; right?

11 MR. SNELL: Form.

12 THE WITNESS: I can't go to "must." I
13 would -- again, I would be -- I would be part of a
14 regulatory -- or part of a team including the
15 regulatory professionals and medical professionals
16 saying what have we got, where are we going to put
17 it, how are we going to teach it? And an IFU is an
18 absolutely reasonable place for it to be as -- one
19 place for it to be.

20 BY MR. SLATER:

21 Q. If that information was considered to be
22 valid -- rephrase.

23 If your company knew that there was a 10
24 to 15 percent worse efficacy rate when a local
25 anesthesia and a cough test was not used, you could

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1 never justify failing to include that information in
2 the IFU for the TVT; correct?

3 A. When you say if you knew it --

4 Q. Right. If you knew. If your company,
5 based on the evidence available to it, was convinced
6 within medical affairs that that is a valid,
7 clinically supported statement, that needs to be in
8 the IFU; right?

9 MR. SNELL: Form.

10 THE WITNESS: So as soon as you say knew,
11 that means to me -- to me that it's the truth in the
12 universe. If it's the truth in the universe and you
13 know it, then I think an IFU statement would be
14 appropriate.

15 BY MR. SLATER:

16 Q. The things that are stated in your IFU are
17 based on the best knowledge available to medical
18 affairs at the time the document is put out for
19 doctors to read; right?

20 A. Yeah.

21 Q. And if medical affairs' knowledge with
22 regard to materially better efficacy to the tune of
23 10 to 15 percent when local anesthesia and a cough
24 test was used met that standard, then it should be in
25 the IFU; right?

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1 MR. SNELL: Form.

2 THE WITNESS: So I said if they knew it.

3 If that's the truth in the universe, then I think

4 it -- it would be included in the IFU.

5 BY MR. SLATER:

6 Q. Let me ask you something about the IFU.

7 It says there's a risk of -- well, rephrase. I'll

8 withdraw that.

9 The foreign body reaction with the TVT is
10 chronic, it is not transitory or short term; right?

11 A. So for any -- any foreign body reaction
12 does have -- in the presence of, obviously, a foreign
13 body does have a -- a time scale to it, yes, and
14 it -- so does it ever go away? I don't think so.

15 Q. The risk of erosion as a result of --
16 rephrase.

17 The risk of erosion with the TVT is not
18 just a transitory, short-term risk, it's a risk for
19 the entire time the person is alive while they have
20 the TVT in their body; right?

21 A. Yeah. I would -- I would refer back to
22 my -- to my medical affairs experts in the field.

23 My understanding is the risk is mostly
24 front loaded, but could you say there's never going
25 to be an erosion late? No, you couldn't say that.

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1 MR. SLATER: Okay. I am going to hand off
2 the questioning to your counsel now.

3 MR. SNELL: Did you have any or are you
4 not going to --

5 MR. SHERIDAN: Yeah, I am going to ask a
6 few questions.

7 MR. SNELL: That's fine. After you get
8 done, I'm just going to take a break and get
9 organized.

10 EXAMINATION

11 BY MR. SHERIDAN:

12 Q. Good afternoon, Doctor.

13 A. Good afternoon.

14 Q. Nice to see you again. I just have a few
15 questions for you.

16 First of all, the IFU that you have in
17 front of you instructs doctors to use a cough test
18 to -- to get the right tension for the TVT; right?

19 A. I don't --

20 MR. SLATER: Stop.

21 I object to the question.

22 MR. SNELL: Yeah. I'm about to --

23 MR. SLATER: Can I talk to you for a
24 second?

25 MR. SNELL: Look at the entire document

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1 before they start making a representation.

2 VIDEO OPERATOR: The time is now 3:59.

3 We are going off the record.

4 (Discussion off the record.)

5 MR. SHERIDAN: I'm withdrawing my
6 question, and I have no questions of the witness.

7 MR. SNELL: Awesome.

8 (Recess, 4:00-4:31 p.m.)

9 VIDEO OPERATOR: The time is now 4:31.
10 We are back on the record.

11 EXAMINATION

12 BY MR. SNELL:

13 Q. Good afternoon, Dr. Hart.

14 A. Good afternoon.

15 Q. I'll ask you, even though I'm sitting
16 aside from you, please focus more towards the camera
17 so the jury can see you.

18 Plaintiffs' counsel has asked you some
19 questions over the past three days of your
20 deposition; correct?

21 A. Correct.

22 Q. And I would just like to follow up on some
23 of those questions, obviously, I'm not going to cover
24 everything that's been discussed with you in three
25 days, and ask you some questions about some of the

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1 exhibits as well that plaintiffs' counsel has shown
2 to you.

3 Is that okay?

4 A. Yes.

5 Q. Plaintiffs' counsel asked you some
6 questions about your background so I won't rehash it
7 but, for the jury's sake, can you tell them what type
8 of surgeon you are?

9 A. I was Board-certified first in general
10 surgery, then cardiothoracic surgery, and then
11 practiced not general surgery but practiced
12 cardiovascular and thoracic surgery.

13 Q. Okay. And when was it that you came to
14 work for Ethicon?

15 A. 2003. July of 2003.

16 Q. And you were an Ethicon employee since
17 that time?

18 A. Yes.

19 Q. Now, I believe you testified to one of
20 plaintiffs' counsel about your role as vice-president
21 of medical operations at Ethicon between the May 2005
22 and the January 2007 time period?

23 A. Yes.

24 Q. What was your role in that position in
25 that 2005 to January 2007 time period?

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1 A. Yeah. So as -- as vice-president of
2 medical operations, I was charged with organizing a
3 medical affairs department.

4 We had -- we had Medical Doctors working at
5 Ethicon and, in fact, they were called -- it was
6 called medical affairs but there -- there was an
7 anticipated need or a recognized need to more
8 formally organize under a set of common systems and
9 processes those work streams so that they could be,
10 number one, more efficient. And so my focus at that
11 time was really just building the department and
12 standardizing how we carried out certain work
13 streams.

14 Q. I believe you earlier testified that one
15 of the things that you were responsible for was
16 standardizing certain processes that needed to be
17 standardized; is that correct or not?

18 A. Medical affairs processes, yes.

19 Q. And during this time period of 2005 to
20 January 2007 did you sit regularly on quality boards?

21 A. No, not -- not as the medical
22 decision-maker.

23 Q. Now, for some point in time Dr. Rami
24 Mahmoud was your boss.

25 A. That's true.

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1 Q. Okay. During the time he was your boss
2 did he sit on the quality boards regularly or did you
3 sit on them in his place?

4 A. He did.

5 Q. Who reported to you beginning in January
6 2007?

7 A. Well, I don't think I can reproduce the
8 exact slate as we sit here.

9 Q. Let me -- let me make it more simple.
10 Did you have different Ethicon companies'
11 medical affairs professionals reporting to you?

12 A. Yes.

13 Q. Such that not only would Women's Health
14 report to you but also Ethicon women's products?

15 A. Ethicon products.

16 Q. Strike that. Strike that. Yeah. That's
17 a bad question.

18 Besides Ethicon Women's Health -- and they
19 reported to you; correct?

20 A. Yes.

21 Q. Ethicon products' medical affairs folks
22 would report to you as well.

23 A. Yes.

24 Q. All right. And in your role, 2007 coming
25 forward, did you rely on the urogynecologists like

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1 Dr. Piet Hinoul and Dave Robinson?

2 A. Yes.

3 MR. SLATER: Objection.

4 BY MR. SNELL:

5 Q. Did -- did Dr. Piet Hinoul report to you?

6 A. Eventually.

7 Q. Did Dave Robinson report to you?

8 A. Yes.

9 Q. Did you rely on those --

10 A. So I'm going to go back.

11 MR. SLATER: Doctor, just one thing I'd
12 just ask you to do is give a little pause before you
13 answer because I may have to object to some of the
14 questions, just give me a chance, then I won't have
15 to speak over you.

16 THE WITNESS: Okay.

17 MR. SHERIDAN: And do we have an agreement
18 that an objection for one is an objection for all?

19 MR. SNELL: Yeah. Yeah.

20 MR. SHERIDAN: So I don't have to repeat
21 and waste --

22 MR. SNELL: Yeah. You don't have to say
23 anything.

24 MR. SLATER: Yeah. Once one attorney
25 objects, it covers everyone.

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1 MR. SHERIDAN: I just wanted to make sure.

2 THE WITNESS: So during that 2005 to 2007
3 period Piet Hinoul did not report to me. I don't
4 think he was part of the company then.

5 MR. SNELL: All right.

6 BY MR. SNELL:

7 Q. At the time Piet Hinoul joined the company
8 did he report up through you?

9 A. Up through me, yes.

10 Q. And did you rely on the expertise of Dr.
11 Hinoul?

12 MR. SLATER: Objection.

13 THE WITNESS: Yes.

14 BY MR. SNELL:

15 Q. Did you rely on the expertise of Dr.
16 Robinson?

17 MR. SLATER: Objection.

18 THE WITNESS: Yes.

19 BY MR. SNELL:

20 Q. Was there a Dr. Aaron Kirkemo who was
21 also -- who also reported up through you at some
22 point?

23 A. Yes.

24 MR. SLATER: Objection.

25 BY MR. SNELL:

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1 Q. Who is Dr. Aaron Kirkemo?

2 A. Aaron -- Aaron was a urologist that came on
3 board and was first, I think, an associate medical
4 director reporting to Dave Robinson. Can't remember
5 for sure whether he was ever promoted to -- to
6 medical director as opposed to associate medical
7 director.

8 Q. Did you rely on Aaron Kirkemo?

9 A. Yes.

10 MR. SLATER: Objection.

11 BY MR. SNELL:

12 Q. Was that a yes or a no?

13 A. Yes, sir.

14 Q. Who is Axel Arnaud?

15 A. Axel Arnaud is a general surgeon, he would
16 say digestive surgeon, based in Paris who has been
17 part -- part -- so for part of his tenure he's been
18 part of medical affairs at Ethicon.

19 Q. Are you aware of whether or not Dr. Arnaud
20 had involvement in the TVT product that you've
21 discussed during your deposition?

22 A. Yes.

23 Q. What about the --

24 A. He did.

25 Q. What about the trans -- strike that.

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1 Did Dr. Arnaud have involvement in the
2 transvaginal mesh product for prolapse?

3 A. Yes.

4 Q. In February 2011 I believe you testified
5 to plaintiffs' counsel your position changed to that
6 of vice-president, evidence-based medicine; is that
7 correct?

8 A. Yeah. And I can't -- I don't know the
9 exact date, but yes, that was the next position.

10 Q. How do you determine what level and type
11 of evidence is needed for a product --

12 MR. SLATER: Objection.

13 BY MR. SNELL:

14 Q. -- when deciding to bring it to market?

15 A. Well, we have a new product development
16 process that brings together cross-functional teams
17 from R&D, regulatory, clinical, medical and others,
18 and depending on the regulatory classification of the
19 product and our understanding of its intended use
20 and -- and characteristics or attributes, we would
21 expect to be able to support a regulatory filing
22 in -- in the countries where we intend to market the
23 product with -- with the team's assessment, including
24 medical affairs, that the product met whatever
25 regulatory requirements were in place.

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1 Q. And is it correct or not that medical
2 affairs does the medical assessment of -- on the
3 safety and efficacy of the device? Let me -- let me
4 take that -- retract that.

5 Is it correct or not that medical affairs
6 does the medical assessment as to the risk-benefit
7 profile of the device?

8 A. Yes.

9 Q. Plaintiffs' counsel showed you some
10 post-marketing surveillance documents earlier in your
11 deposition.

12 Do you recall those, in general?

13 A. In general, yes.

14 Q. What is post-marketing surveillance?

15 A. Post-market surveillance is a process
16 within the quality organization that receives
17 information or inputs regarding the performance of
18 products in the marketplace and, you know,
19 categorizes, analyzes those data and then, of course,
20 on an ongoing basis sort of benefit-risk evaluations
21 will be undertaken.

22 Q. Earlier in your deposition plaintiffs'
23 counsel asked you questions about some of these
24 quality documents and whether a certain word was or
25 was not included explicitly in the document.

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1 Do you, in general, recall that line of
2 questioning?

3 MR. SLATER: Objection.

4 THE WITNESS: Yeah, in general. Yeah.

5 BY MR. SNELL:

6 Q. Regardless of whether a certain word is
7 set forth explicitly in a quality document, would
8 that mean that a product is not safe and effective?

9 MR. SLATER: Objection.

10 MR. SHERIDAN: Objection.

11 THE WITNESS: No.

12 BY MR. SNELL:

13 Q. Now, let's turn to Exhibit 1345.

14 A. I have it.

15 Q. This is the December 2nd, 1999,
16 biocompatibility risk assessment for the Prolene Soft
17 mesh; correct?

18 A. Correct.

19 Q. And it was done by Thomas Barbolt, Ph.D.,
20 D.A.B.T.?

21 A. Correct.

22 Q. Who is Dr. Thomas Barbolt?

23 A. Tom Barbolt is a toxicologist who worked at
24 Ethicon for a very long period of time, and I knew
25 him as -- as part of the preclinical team in

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1 toxicology with specific -- well, maybe not specific
2 but certainly a broad-based knowledge around our
3 suture platform. But then I worked with him,
4 actually, for probably two or three years in a
5 completely different capacity or different --
6 different type of product so I got to know him very
7 well under that -- that circumstance.

8 Q. And did you come to value his experience?

9 MR. SLATER: Objection.

10 MR. SHERIDAN: Objection.

11 THE WITNESS: I did.

12 BY MR. SNELL:

13 Q. Do you believe that he was qualified for
14 the job that he performed?

15 MR. SLATER: Objection.

16 MR. SHERIDAN: Objection.

17 THE WITNESS: Yes.

18 BY MR. SNELL:

19 Q. Did he at any times report up to you?

20 A. No.

21 Q. Now, plaintiffs' counsel --

22 A. Oh, wait. Hang on. Hang on.

23 During the period of time that I was VP of
24 evidence-based medicine I did oversee preclinical,
25 and I can't remember whether Tom had retired by then

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1 or not. I think he had.

2 Q. Okay. Now, plaintiffs' counsel read or
3 had you read some of the parts of this two-page
4 document.

5 Do you recall that?

6 A. I do.

7 Q. I'd like to ask you to read a couple
8 things and comment on them.

9 First, what was the reason behind this
10 biocompatibility risk assessment?

11 A. Well, this would be a standard activity
12 during early development or during development of a
13 new product. And the purpose would be to do a
14 risk -- as it says, a biocompatibility risk
15 assessment based on what we know in the material
16 already and/or what Dr. Barbolt knew already and
17 against various standards and regulations.

18 Q. And here all that they were doing was
19 comparing the new construction, which was going to
20 use a smaller-diameter polypropylene filament.

21 MR. SLATER: Objection.

22 THE WITNESS: That's how I read it, yes.

23 BY MR. SNELL:

24 Q. Now, plaintiffs' counsel asked you some
25 questions about your experience as a surgeon and

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1 whether you had used Prolene sutures.

2 Do you recall those questions?

3 A. I do.

4 Q. The sentence states in the second
5 paragraph, there is an extensive history of safe
6 clinical use with polypropylene, specifically Prolene
7 mesh and natural and blue Prolene suture, that
8 demonstrates that this material is one of the most
9 inert biomaterials available for implantation.

10 Did I read that correctly?

11 A. You did.

12 Q. Now, is that consistent or inconsistent
13 with your experience as a surgeon using Prolene?

14 A. Absolutely consistent.

15 Q. Plaintiffs' counsel asked you some
16 questions about cytotoxicity, which is referenced in
17 this document.

18 Do you recall those?

19 A. I do.

20 Q. In your experience, is Prolene cytotoxic?

21 MR. SHERIDAN: Objection.

22 MR. SLATER: Objection.

23 THE WITNESS: No. So my personal
24 experience as a surgeon, obviously, in cardiovascular
25 patients for 10 years of training, 30 -- and 20 years

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1 of practice, used it all day, every day -- I don't
2 think I could accurately estimate how much Prolene I
3 used in cardiovascular procedures, including many
4 procedures where patients had to be re-operated on,
5 and so I would see evidence or I would see those
6 sutures again -- and my experience was of all the
7 sutures that I encountered on a second or third
8 operation, Prolene, on average, significantly was
9 less encased with fibrotic scars than other sutures
10 which would be braided or otherwise.

11 So my -- you know, my clinical experience
12 was that in those cardiovascular tissues and others
13 where I used them I had no evidence for cytotoxicity
14 or any other untoward problem.

15 BY MR. SNELL:

16 Q. There was an objection so I'm going to
17 just ask you a basic question: What was your
18 experience with Prolene sutures?

19 A. Well, as a cardiovascular surgeon for
20 decades, it's been the gold standard for vascular
21 anastomoses so I would -- I would estimate that, you
22 know, 90 or 95 percent of my experience with Prolene
23 sutures was in that setting, and it ranged from
24 coronary bypass surgery, where, you know, on average,
25 a patient would have three bypass grafts placed,

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1 which would equate to, on average, five vascular
2 anastomoses and would also be used at other parts of
3 the operation on cardiovascular tissue. In
4 peripheral vascular surgery, similarly, to construct
5 vascular anastomoses.

6 One of the -- you know, one of the more
7 attractive or attractive attributes was its long-term
8 durability. I mean, operating on people for a second
9 time.

10 So I always go back to in the -- in the
11 '50s or '60s, when abdominal aortic aneurysms were
12 first being repaired with synthetic grafts or
13 polyester grafts, they were implanted with -- with,
14 typically, silk sutures. In that day and age, silk
15 sutures were felt to be non-absorbable or permanent
16 and, indeed, they're not, and so a number of patients
17 would come back in -- so that a polyester graft never
18 heals to the aorta or to the recipient vessel and
19 requires mechanical attachment permanently because if
20 the mechanical attachment is lost and there's not --
21 and there is no real healing between polyester and
22 the aorta, the two vessels actually separate in
23 some -- in some patients. Now, they don't do it
24 acutely so they don't, you know, exsanguinate, but
25 you would get a fibrous capsule in between there that

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1 would actually become aneurysm. I operated on a
2 number of people -- a number of people in the, I
3 guess '80s -- '70s and '80s.

4 That just doesn't occur with Prolene. You
5 re-operate on somebody -- my most poignant experience
6 was -- and I've -- I've told this to a lot of
7 people -- the first week I was in practice or the
8 second week I was in practice, I think 1983, I did a
9 coronary bypass on a patient who showed up 20 years
10 later about a week before I left practice and needed
11 a second operation.

12 I first declined to operate on him. I
13 said, you know, Mr. So and So, I'll be leaving
14 practice in a week or so and -- and -- but he
15 convinced me to do so, and I left him under the care
16 of my partners.

17 But I remember distinctly because I knew I
18 was coming to Ethicon in a few days or a week, and
19 when I dissected his heart free so I could do his new
20 bypasses, one of the bypasses, which was still
21 working or was not working, I should say, you know, I
22 came to that Prolene suture, I needed to remove it to
23 continue with the dissection, and I remember cutting
24 it out and holding it up and saying, oh, my gosh, you
25 know, this is exactly the way it looked 20 years ago

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1 and I'm going to this company in a week. It isn't --
2 I just -- it was striking to say that it's, you know,
3 remarkable material.

4 So my experience was it -- it was the best
5 and absolute gold standard for vascular anastomoses
6 for decades and continues to be so to this day.

7 Q. You mentioned vascular anastomoses.

8 A. Oh.

9 Q. What is that? Can you explain that to the
10 jury so --

11 A. I can.

12 Q. Put that in a laymen's terms.

13 A. Yeah. If you have to connect two blood
14 vessels so that blood flow can come down through one
15 blood vessel into another one, you have to attach
16 them and sew them together either end to end or
17 what's called end to side, so it's that attachment
18 that's called the anastomosis.

19 Q. And did the Prolene -- in your experience,
20 did the Prolene respond to the stresses put on it by
21 the body?

22 MR. SLATER: Objection.

23 THE WITNESS: Yes.

24 BY MR. SNELL:

25 Q. How so?

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1 A. Well, so -- so think about that when
2 you're -- when you're attaching a polyester or Dacron
3 graft to the aorta and it has to work forever and
4 you've got the suture line with the anastomosis, your
5 pulse pressure is one -- one beat or 80 beats per
6 minute times however many minutes there are in an
7 hour, times 20 years, and they do respond and stay
8 with mechanical or their -- their mechanical
9 integrity stays intact.

10 Q. Now, besides some of the testing that
11 plaintiffs had you read into the record from this
12 document, I'd like to go over some of the other
13 testing set forth.

14 It states, the chronic systemic toxicity
15 and carcinogenicity of this material was evaluated
16 using natural and blue Prolene suture in the rat and
17 dog.

18 Did I read that correctly?

19 A. You did.

20 Q. And carcinogenicity is what, Doctor?

21 A. That's the propensity for a material or a
22 chemical or something to cause cancer.

23 Q. And it states, it indicates that this
24 material was well tolerated and non-carcinogenic?

25 A. Non-carcinogenic.

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1 Q. Non-carcinogenic. Thank you.

2 A. It does say that.

3 Q. It states, this negative carcinogenicity
4 result and long-term clinical experience preclude the
5 need to conduct genotoxicity testing.

6 MR. SLATER: Objection.

7 BY MR. SNELL:

8 Q. Did I read that correctly?

9 MR. SLATER: Objection.

10 THE WITNESS: You did.

11 BY MR. SNELL:

12 Q. And then it goes on to talk about a number
13 of other intramuscular and ophthalmic implantation
14 studies have been conducted as well.

15 MR. SLATER: Objection.

16 BY MR. SNELL:

17 Q. Is that correct or not?

18 MR. SLATER: Objection.

19 THE WITNESS: It does say that.

20 BY MR. SNELL:

21 Q. It states, the results indicated that this
22 gold-standard material was well tolerated and without
23 adverse effects.

24 Did I read that correctly?

25 MR. SLATER: Objection.

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1 THE WITNESS: Yes.

2 BY MR. SNELL:

3 Q. And is that consistent or inconsistent
4 with your experience?

5 A. It's consistent.

6 Q. It says, in addition, an intramuscular
7 tissue reaction study was conducted in rats where
8 Prolene mesh was used as the control article. The
9 results indicated that the tissue reaction was
10 generally mild and the presence of the mesh did not
11 impair the healing response.

12 Did I read that correctly?

13 MR. SLATER: Objection.

14 THE WITNESS: You did.

15 BY MR. SNELL:

16 Q. Is that consistent or inconsistent with
17 your experience with Prolene?

18 A. Consistent.

19 MR. SLATER: Objection.

20 BY MR. SNELL:

21 Q. Turn, if you would, to the TVT 510(k)
22 plaintiffs' counsel asked you about. It's been
23 marked as Exhibit T-3142.

24 MR. SNELL: Bless you.

25 THE WITNESS: Yeah.

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1 BY MR. SNELL:

2 Q. And plaintiffs' counsel pointed out the
3 results of one of the cytotoxicity testings that were
4 positive.

5 Do you recall that?

6 A. Yes.

7 Q. And are cytotoxic --

8 MR. SLATER: Objection to the form of the
9 question.

10 BY MR. SNELL:

11 Q. Are cytotoxic -- are the cytotoxic tests
12 that plaintiffs' counsel pointed out to you, are
13 those conducted in people?

14 A. No.

15 Q. Well, what are they conducted in?

16 A. Cell -- cell culture, I believe. But --
17 but -- but individual cells or -- yeah, individual
18 cells in -- in preclinical benchtop testing in
19 glassware, I presume.

20 Q. Petri dish?

21 MR. SLATER: Objection.

22 BY MR. SNELL:

23 Q. Is that the type of --

24 A. Yeah.

25 Q. -- testing --

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1 A. Yeah.

2 Q. -- medium that these types of --

3 A. I wouldn't say --

4 Q. -- cell lines would be --

5 A. It wouldn't necessarily be Petri medium but
6 it would be in glassware in solution, I believe.

7 Q. Okay. Turn to Page 41. The Bates number
8 is 286.

9 A. Okay.

10 MR. SLATER: What Page?

11 MR. SNELL: Sure. 41. 286.

12 BY MR. SNELL:

13 Q. This is a section about biocompatibility
14 testing plaintiffs' counsel asked you some questions
15 about.

16 A. Okay.

17 Q. One of the things I believe plaintiffs'
18 counsel pointed out was that for this ISO elution
19 test there was moderate to severe cytotoxicity; is
20 that correct?

21 A. Yes.

22 Q. The results, it states, of the ISO agarose
23 diffusion test were non-cytotoxic.

24 Did I read that correctly?

25 MR. SLATER: Objection.

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1 THE WITNESS: Yes.

2 BY MR. SNELL:

3 Q. Now, would medical affairs or preclinical
4 be the ones doing these types of tests?

5 A. No. Oh, preclinical. Sorry.

6 Q. Okay. Down at the last paragraph,
7 plaintiffs' counsel had you read the part where it
8 says, the polypropylene mesh component of the sterile
9 TVT device was cytotoxic in only the elution test,
10 suggesting cytotoxic potential in this sensitive test
11 system.

12 Do you recall that?

13 MR. SLATER: Objection.

14 THE WITNESS: I -- I do.

15 BY MR. SNELL:

16 Q. I'd like you to -- can you read the next
17 sentence, please.

18 A. Aloud?

19 Q. Sure.

20 A. However, the long history of safe clinical
21 use of polypropylene as mesh and suture products
22 suggests strongly that this material is inherently
23 biocompatible and that potential -- and that the
24 potential toxicity -- cytotoxicity observed and is
25 self-limiting and -- is self-limiting and minimal

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1 when compared to the implantation procedure itself.

2 MR. SHERIDAN: Object to the question.

3 Sorry for the late objection.

4 MR. SLATER: Didn't I -- I objected to
5 that question; right? Oh, I thought I did.

6 BY MR. SNELL:

7 Q. Turn to the next page. It states, there
8 is abundant clinical data, about 500 patients,
9 including over 200 documented cases, which
10 demonstrates that the use of the TVT device, which
11 includes the implanted polypropylene mesh tape, has
12 fewer complications in terms of tissue reaction than
13 other comparable devices.

14 First of all, did I read that correctly?

15 MR. SLATER: Objection.

16 THE WITNESS: Yes.

17 BY MR. SNELL:

18 Q. Are you aware about -- strike that.

19 Are you aware of whether other types of
20 mesh like Gore-Tex have been tried before Prolene by
21 Professor Ulmsten?

22 A. I have some awareness, yes.

23 Q. And do you know whether the reported rates
24 of rejection or mesh complications were higher with
25 the other meshes before the Prolene?

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1 A. I think that's -- yes, I think the
2 publication states that it was higher.

3 Q. I believe plaintiffs' counsel asked you
4 questions about whether cytotoxicity would cause mesh
5 exposures.

6 Do you recall, in general, that topic?

7 A. Yes.

8 MR. SLATER: Objection to the form of the
9 question.

10 MR. SNELL: Let me back up, then.

11 BY MR. SNELL:

12 Q. Is the Prolene mesh cytotoxic, in your
13 opinion?

14 MR. SLATER: Objection.

15 THE WITNESS: No.

16 BY MR. SNELL:

17 Q. Are Prolene sutures cytotoxic, in your
18 opinion?

19 A. No.

20 MR. SLATER: Objection.

21 THE WITNESS: No.

22 BY MR. SNELL:

23 Q. To your understanding or knowledge, are
24 mesh exposures due to alleged cytotoxicity?

25 MR. SLATER: Objection.

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1 THE WITNESS: Can you say it one more
2 time? Sorry.

3 MR. SNELL: Sure.

4 BY MR. SNELL:

5 Q. Are -- are mesh exposures due to alleged
6 cytotoxicity?

7 MR. SLATER: Objection.

8 THE WITNESS: I don't -- I can't say
9 that's true.

10 BY MR. SNELL:

11 Q. Do you have Exhibit 1312 in front of you?

12 A. Uh-huh. Yes.

13 Q. This is the post-market surveillance
14 report for Prolift that plaintiffs' counsel showed
15 you?

16 MR. SHERIDAN: Could you just say the
17 Bates number for the record?

18 MR. SNELL: Yes. ETH.MESH.04121282.

19 MR. SHERIDAN: Okay.

20 MR. SLATER: Do you have another copy of
21 that?

22 MR. SNELL: Let me see.

23 Let's go off the record. I'm going to
24 have to look through here.

25 VIDEO OPERATOR: The time is now 5:00.

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1 We are going off the record.

2 (Discussion off the record.)

3 VIDEO OPERATOR: The time is now 5:05.

4 We are back on the record.

5 BY MR. SNELL:

6 Q. Dr. Hart, did Ethicon Women's Health &
7 Urology medical affairs perform risk-benefit
8 evaluations on its products?

9 MR. SLATER: Objection.

10 THE WITNESS: Yes.

11 BY MR. SNELL:

12 Q. You were asked some questions about when a
13 device could be put on the market.

14 In general, do you recall those types of
15 questions?

16 A. No. Is that from weeks ago?

17 Q. It was from months ago.

18 Let me ask you this, then: You were asked
19 about different women's health products over the
20 course of your deposition; correct?

21 A. Correct.

22 Q. Do you recall questions about, for
23 instance, the Prolift and whether or not it should
24 have been brought to market?

25 A. Generally, yeah.

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1 Q. Okay. If there is reasonable assurance of
2 safety and effectiveness, is it okay to put a product
3 on the market?

4 MR. SLATER: Objection.

5 THE WITNESS: So you would -- you would
6 line up the level of evidence against the regulatory
7 requirements for whatever classification of device
8 you were talking about. But, yeah, that would be --
9 that would be a standard on the device side or a
10 regulatory standard.

11 BY MR. SNELL:

12 Q. I'd like to -- I'm just going to give you
13 my copy of Exhibit T-1311. It was the November 2nd,
14 2010, Prolift post-market surveillance report review
15 session that plaintiffs' counsel asked you questions
16 about, and I believe you pointed out that Dave
17 Robinson from medical affairs was present.

18 A. Okay.

19 Q. I'd just like you to read the very last
20 bullet point that's under Section MM-7 about whether
21 or not the Prolift device at that time was performing
22 as expected.

23 MR. SHERIDAN: Objection.

24 MR. SLATER: Objection.

25 THE WITNESS: So I can read it --

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1 MR. SLATER: I've got it.

2 MR. SHERIDAN: Oh, okay. Sorry. We'll
3 have the reporter --

4 MR. SLATER: She got it.

5 THE WITNESS: Read it out loud?

6 MR. SNELL: Yes, please.

7 THE WITNESS: Yeah. Prolift is performing
8 as intended and is a safe and effective approach for
9 the surgical treatment of pelvic organ prolapse.
10 BY MR. SNELL:

11 Q. Now, plaintiffs' counsel, I believe,
12 marked as an exhibit the Iglesia study that concerned
13 the Prolift device.

14 Do you recall that?

15 A. I do.

16 Q. And after the Iglesia study came out did
17 Ethicon investigate the safety and effectiveness of
18 Prolift?

19 MR. SLATER: Objection.

20 THE WITNESS: Yes.

21 BY MR. SNELL:

22 Q. I believe you testified at the first day
23 of your deposition that Dr. Piet Hinoul did an
24 analysis and review and presentation to you and some
25 others.

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1 A. Correct.

2 Q. Okay.

3 MR. SNELL: Do you have exhibit stickers?

4 I don't think I've marked this, Adam. I
5 don't think somebody marked this.

6 MR. SLATER: I'm looking for something
7 else.

8 MR. SNELL: I'm just going to mark it.

9 MR. SLATER: You're marking new exhibits?

10 MR. SNELL: I'm just going to mark it.
11 Yeah. It was discussed but it wasn't marked.

12 MR. SLATER: Sweet.

13 MR. SHERIDAN: What's our number?

14 MR. SNELL: I'm going to just call it Hart
15 D-1.

16 MR. SHERIDAN: Wait. Wait. What number?

17 MR. SNELL: Hart D-1.

18 MR. SLATER: That's fine. Don't worry
19 about it. It all comes up on Golkow's site anyway.

20 MR. SNELL: Yeah.

21 MR. SLATER: Hart D-1?

22 MR. SNELL: Yes.

23 MR. SLATER: With the placeholder first
24 and then the document?

25 MR. SNELL: Yes.

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1 MR. SLATER: Is that how you marked it?

2 MR. SNELL: Yeah.

3 MR. SLATER: Excellent. Well done.

4 (Exhibit Hart D-1 was marked for
5 identification.)

6 BY MR. SNELL:

7 Q. Can you identify what Exhibit D-1 is,
8 Doctor?

9 A. I believe this is the presentation that
10 Piet made that you just -- at the meeting or the --
11 yeah, at the meeting that you just referenced.

12 Q. And, in general, can you tell me what the
13 presentation encompassed?

14 A. My recollection was -- and I haven't looked
15 at all these slides in a long time -- that Piet was
16 asked and produced this document that would be, you
17 know, sort of a re-review of the available -- first
18 of all, review of the sort of the -- the disease
19 states and background of the procedures historically
20 and current and then to review what's known in the
21 literature and from elsewhere, but mostly the
22 literature, I guess, regarding performance of,
23 relative performance, I guess, of some of the
24 procedures that are available, including the -- the
25 mesh repairs.

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1 Q. And in the presentation did Dr. Hinoul
2 cover clinical studies pertaining to the Prolift
3 device?

4 MR. SLATER: Objection.

5 THE WITNESS: Yes. I mean, yeah. Excuse
6 me. Yes.

7 BY MR. SNELL:

8 Q. Did he -- did he address -- strike that.

9 Did Dr. Hinoul's November 2010 analysis
10 also look at exposure and erosion rates?

11 MR. SLATER: Objection.

12 THE WITNESS: Yes.

13 BY MR. SNELL:

14 Q. Did Dr. Hinoul's November 2010 analysis
15 address other complications, such as bleeding
16 complications?

17 A. Yes.

18 MR. SLATER: Objection.

19 THE WITNESS: Yes.

20 BY MR. SNELL:

21 Q. Visceral injury?

22 A. Yes.

23 Q. Fistulas?

24 MR. SLATER: Objection.

25 MR. SHERIDAN: Objection.

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1 THE WITNESS: Yes.

2 MR. SLATER: Objection.

3 My intention was to object to each
4 question. It's hard to get them all out before the
5 answers.

6 BY MR. SNELL:

7 Q. Did Dr. Hinoul analyze pain
8 postoperatively?

9 MR. SLATER: Objection.

10 THE WITNESS: Yes.

11 BY MR. SNELL:

12 Q. Did Dr. Hinoul evaluate mesh retraction?

13 MR. SLATER: Objection.

14 THE WITNESS: I presume. I'd have to see
15 it on the page.

16 BY MR. SNELL:

17 Q. Turn to the -- the header slide that says,
18 pain, IUGA, 2001 to 2008.

19 A. Yeah. Yes.

20 Q. So we're on the page that says, pain,
21 IUGA, 2001 to 2008.

22 Are you there? Are you there?

23 A. Yes, I am. I'm sorry.

24 MR. SLATER: Can you give me one second?

25 MR. SNELL: Absolutely.

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1 MR. SLATER: What page is it?

2 MR. SNELL: It says, pain, IUGA, '01 to
3 '08.

4 THE WITNESS: Yeah. Unfortunately,
5 they're not numbered.

6 MR. SLATER: Yeah. I'm trying to figure
7 out -- here it is. Got it.

8 MR. SNELL: Got it?

9 BY MR. SNELL:

10 Q. So the bottom column states, mesh
11 retraction?

12 A. Yes.

13 Q. Did Dr. Hinoul assess mesh retraction?

14 MR. SLATER: Objection.

15 THE WITNESS: Yes.

16 BY MR. SNELL:

17 Q. Turn to the next page. Title of this
18 slide is, dyspareunia; correct?

19 A. Correct.

20 Q. Did Dr. Hinoul look at the literature with
21 regard to dyspareunia after prolapse surgery?

22 A. Yes.

23 MR. SLATER: Objection.

24 MR. SHERIDAN: Object.

25 BY MR. SNELL:

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1 Q. Did Dr. Hinoul look to the literature with
2 regard to de novo dyspareunia after prolapse surgery?

3 MR. SLATER: Objection.

4 THE WITNESS: Yes.

5 BY MR. SNELL:

6 Q. And this was a presentation made, in part,
7 to you; correct?

8 A. Correct.

9 Q. And for the de novo dyspareunia rates
10 reported here across the different prolapse surgeries
11 how did Prolift's de novo dyspareunia rate compare?

12 MR. SHERIDAN: Objection.

13 THE WITNESS: Favorably.

14 BY MR. SNELL:

15 Q. It says, 2010 PubMed update, on the next
16 slide.

17 A. Uh-huh.

18 Q. And the slides that follow that. And is
19 that correct?

20 A. That's correct.

21 Q. What is PubMed?

22 A. PubMed is a searchable database where
23 you -- a person can go in and enter search terms and
24 the -- the -- the program will -- will search medical
25 literature, basically.

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1 Q. Did Dr. Hinoul do a PubMed search?

2 A. Yes.

3 Q. The next page or series of pages talks
4 about the Iglesia study, which plaintiffs' counsel
5 marked and showed to you; correct?

6 A. Correct.

7 Q. And it says that the subjective cure of
8 bulge symptoms in the mesh arm was 93.3 percent.

9 Did I read that correctly?

10 MR. SLATER: Objection.

11 THE WITNESS: You did.

12 BY MR. SNELL:

13 Q. And as plaintiffs' counsel, I believe,
14 pointed out, there were five vaginal mesh exposures
15 in the Iglesia study?

16 A. Yes.

17 Q. Do you know whether there were suture
18 erosions in the non-mesh arm of the Iglesia study?

19 A. Yes.

20 Q. Do you remember how many suture erosions
21 occurred in the Iglesia study?

22 A. My recollection is similar in incidence.

23 Q. Five mesh exposures, five suture erosions?

24 MR. SLATER: Objection.

25 THE WITNESS: Yeah.

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1 MR. SNELL: We'll look at it in a moment.

2 BY MR. SNELL:

3 Q. At the conclusion of this mesh platform
4 review in November 2010, was a determination made by
5 Ethicon medical affairs as to whether the Prolift was
6 safe and effective?

7 MR. SLATER: Objection.

8 THE WITNESS: Yes.

9 BY MR. SNELL:

10 Q. What was that determination?

11 A. That it was safe and effective.

12 Q. And had Ethicon medical affairs prior to
13 that already determined that Prolift was safe and
14 effective?

15 MR. SLATER: Objection.

16 THE WITNESS: Yes.

17 (Exhibit Hart D-2 was marked for
18 identification.)

19 BY MR. SNELL:

20 Q. Doctor, I'm handing you Exhibit Hart D-2.
21 Let me -- hold on. Let's back up, make sure I didn't
22 give you a highlighted copy.

23 MR. SNELL: Here you go, Adam.

24 BY MR. SNELL:

25 Q. I've handed you Hart Exhibit D-2.

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1 Do you recognize this study to be the
2 followup to the Iglesia study?

3 A. I do.

4 Q. The lead author in this publication is
5 Andrew I. Sokol.

6 Do you see that?

7 A. I do.

8 Q. Turn -- let's go pretty much to the very
9 back, Page E-6.

10 A. E-6. Okay.

11 Q. This is an electronic printout but, as
12 plaintiffs' counsel pointed out, of the 32 mesh
13 subjects, five women had mesh exposures; correct?

14 A. Correct.

15 Q. Look over at the next column on the right.
16 How many of the non-mesh participants had
17 suture exposures?

18 A. Five.

19 Q. And those were apical Gore-Tex suture
20 exposures, it states; correct or not?

21 A. Correct.

22 Q. And two of those five women had some
23 complaints that they required suture removal at six
24 and nine months after the procedure; is that correct
25 or not?

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1 A. That's correct.

2 Q. So the same number of women in the Prolift
3 arm of the study had a mesh exposure as the women in
4 the non-mesh arm had a suture exposure.

5 MR. SLATER: Objection.

6 THE WITNESS: Correct.

7 BY MR. SNELL:

8 Q. Turn to the next page, Table 4,
9 dyspareunia.

10 Do you see that?

11 A. I do.

12 Q. Now, 12 months after the operation, in the
13 Prolift mesh group the dyspareunia percentage was 6.7
14 percent in the Prolift arm; correct?

15 MR. SLATER: Objection.

16 THE WITNESS: Correct.

17 MR. SNELL: Strike that.

18 BY MR. SNELL:

19 Q. What was the dyspareunia percentage in the
20 Prolift arm?

21 A. 6.7 percent.

22 Q. And what was the dyspareunia percentage in
23 the no-mesh arm at 12 months after the operation?

24 A. 18.8 percent.

25 Q. Now, those two were not statistically

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1 significantly different; is that correct or not?

2 A. That's correct.

3 Q. Numerically, the dyspareunia was lower in
4 the Prolift arm than in the no-mesh arm in the Sokol
5 paper; is that correct or not?

6 MR. SLATER: Objection.

7 THE WITNESS: That's correct.

8 BY MR. SNELL:

9 Q. And the Iglesia/Sokol study had a small
10 number of patients involved.

11 MR. SLATER: Objection.

12 THE WITNESS: Yes.

13 BY MR. SNELL:

14 Q. Well, let me just ask it this way: What
15 is your opinion as to the number of patients involved
16 in the Iglesia study?

17 MR. SLATER: Objection.

18 THE WITNESS: It's a small number, about
19 15 or 16 in each arm, after one-year followup.

20 BY MR. SNELL:

21 Q. Those -- that were assessed for
22 dyspareunia?

23 A. Uh-huh.

24 Q. You have to say yes or no.

25 A. Yes.

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1 MR. SLATER: Objection.

2 BY MR. SNELL:

3 Q. Do you have Exhibit T-1317, the April
4 21st, 2011 --

5 A. I do now.

6 Q. -- PowerPoint?

7 MR. SLATER: Do you have it for me?

8 MR. SHERIDAN: What are the Bates numbers?

9 MR. SNELL: Let's see.

10 MR. SLATER: Well, if you're going to go
11 through a big PowerPoint, I'm going to have to have
12 it in front of me.

13 MR. SNELL: Okay.

14 MR. SLATER: And, listen, no -- no joking
15 around, I'm not trying to be facetious, we're going
16 to be here a long time. This -- this PowerPoint
17 alone I could be 45 minutes with.

18 MR. SNELL: I could be an hour with it
19 but, I mean, I'm just going to ask him a couple
20 questions.

21 MR. SLATER: I don't really -- I'm just
22 telling you flat-out --

23 MR. SNELL: I don't know if I have -- see,
24 I've got my comments. I would give you mine but I've
25 got stuff all over it.

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1 MR. SLATER: Well, I mean, look, if you're
2 going to question Dr. Hart on a -- on a lengthy
3 PowerPoint, I'm sorry, but I need a copy of it. I
4 just can't remember all the stuff myself. I'm not
5 that good.

6 MR. SNELL: Let's go off the record for a
7 minute.

8 MR. SLATER: Okay. Off the record.

9 VIDEO OPERATOR: The time is now 5:24.
10 Off the record.

11 (Recess, 5:24-5:40 p.m.)

12 VIDEO OPERATOR: Time is now 5:40.
13 We are back on the record.

14 BY MR. SNELL:

15 Q. Doctor, we're looking at Exhibit T-1317,
16 the April 21st, 2011, PowerPoint from the meeting
17 with the FDA.

18 It was early marked -- earlier marked in
19 your deposition; is that correct?

20 A. Yes.

21 Q. And this -- I believe you testified to
22 plaintiffs' counsel that this was the meeting you
23 attended in person?

24 A. I did.

25 Q. Okay. And in preparation for this meeting

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1 did Ethicon medical affairs do a risk-benefit
2 assessment of its pelvic floor repair products?

3 MR. SLATER: Objection.

4 MR. SHERIDAN: Objection.

5 THE WITNESS: Yes, as part of putting this
6 material together.

7 BY MR. SNELL:

8 Q. As part of putting this material together,
9 did Ethicon medical affairs do a risk-benefit
10 assessment of its stress urinary incontinence
11 products?

12 MR. SHERIDAN: Objection.

13 MR. SLATER: Objection.

14 THE WITNESS: Yes.

15 BY MR. SNELL:

16 Q. And what was Ethicon medical affairs'
17 assessment with regard to its pelvic floor repair
18 products?

19 A. Same conclusion as from the previous 2010
20 review, safe -- that the products were safe and
21 effective -- and effective.

22 Q. And what was Ethicon medical affairs'
23 assessment of its stress urinary incontinence
24 devices --

25 A. Same.

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1 Q. -- at this time?

2 A. Same.

3 Q. Which is?

4 A. Products were -- were performing safely and
5 effectively.

6 Q. On Page 3, third bullet point, it states,
7 Ethicon is the industry leader in women's health.

8 Did I read that correctly?

9 A. Yes.

10 MR. SLATER: Objection.

11 BY MR. SNELL:

12 Q. Most research products and published
13 literature.

14 Did I read that correctly?

15 MR. SLATER: Objection.

16 THE WITNESS: Yes.

17 BY MR. SNELL:

18 Q. Plaintiffs' counsel asked you some
19 questions about the Ethicon TVT device?

20 A. Yes.

21 Q. Do you know how many, approximately how
22 many randomized, controlled trials have been done
23 concerning the Ethicon TVT device?

24 A. I think it's on the order of between 150
25 and 200.

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1 Q. And does that include the TVT retropubic,
2 the TVT obturator and the TVT -- strike that.

3 Does that include those two mid-urethral
4 slings?

5 A. Yes.

6 MR. SLATER: Objection.

7 BY MR. SNELL:

8 Q. The -- I think about the seventh page has
9 a clinical overview, Piet Hinoul, M.D., Ph.D., page.
10 Do you see that?

11 MR. SLATER: What page did you say?

12 MR. SNELL: I think it's about the
13 seventh. Again, these aren't numbered. Well,
14 actually, they are.

15 THE WITNESS: Some of them are numbered
16 but I do -- it's -- it's --

17 BY MR. SNELL:

18 Q. So it would be Number 9. Let me re-ask
19 it.

20 If you flip through the PowerPoint, the
21 ninth page begins, the clinical overview by Piet
22 Hinoul; is that correct or not?

23 A. It is.

24 Q. Okay. And turn back, if you would, to
25 Page 33 --

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1 A. Uh-huh.

2 Q. -- the Prolift PubMed update, February
3 2011.

4 Do you see that?

5 A. Uh-huh. Yes.

6 Q. And did Ethicon medical affairs do an
7 update on its PubMed search regarding Prolift in lieu
8 of this meeting?

9 MR. SLATER: Objection.

10 THE WITNESS: Yes.

11 BY MR. SNELL:

12 Q. During the deposition plaintiffs' counsel
13 had asked you questions about the complications of
14 mesh exposure and mesh erosion; is that correct?

15 A. That's correct.

16 Q. Turn to Page 32.

17 Now, what are these photos on Page 32?

18 A. They're titled, mesh exposure versus
19 erosion. And the -- the photo -- the photo on the
20 left would be an example of a mesh exposure
21 intravaginally and the photo on the right would be
22 some mesh exposed intraluminally in what appears to
23 be the GI tract but...

24 Q. Is there a difference between mesh
25 exposures and mesh erosion, to your understanding?

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1 A. Well, as I -- as I currently use the words
2 and many do, yes.

3 Q. Okay.

4 A. Sorry. I bumped my --

5 Q. That's all I have on that.

6 Plaintiff asked you some questions about
7 the Altman 2011 Prolift versus anterior colporrhaphy
8 randomized, controlled trial.

9 Do you recall that?

10 A. Previously; right? Yes.

11 Q. Yeah. Do you have a general recollection
12 of how Prolift performed, compared to colporrhaphy
13 anatomically?

14 A. I would want to be refreshed if I was going
15 to answer.

16 Q. Okay.

17 MR. SLATER: Do you seriously want to go
18 through the results of the Altman study?

19 MR. SNELL: Yeah. Well, you asked him
20 about the complications. I'm going to ask him just a
21 few questions about it.

22 MR. SLATER: Listen, do whatever you want.

23 MR. SNELL: That's fine. I'm only going
24 to ask him a couple of questions about it.

25 MR. SLATER: That's fine. I'm, obviously,

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1 going to follow up with all the other data and it's
2 going to get us into a -- we'll be on the
3 merry-go-round.

4 MR. SNELL: I'm going to give him my copy,
5 if that's okay, just ask him about Table 2. Is that
6 okay?

7 MR. SLATER: I -- I'm not here -- I'm not
8 the teacher. I'm the bad student who keeps getting
9 kicked out of the room.

10 BY MR. SNELL:

11 Q. Doctor, I'm handing you Table 2 of the
12 Altman study.

13 MR. SHERIDAN: What exhibit is it?

14 MR. SNELL: It was previously marked --
15 look at the front page, Doctor.

16 THE WITNESS: 858.

17 MR. SLATER: It wasn't marked during this
18 deposition. It wasn't used during this deposition.

19 MR. SNELL: No. It was used during this
20 deposition.

21 MR. SLATER: The actual study?

22 MR. SNELL: Yes, the actual study.

23 MR. SLATER: Are you sure about that?

24 MR. SNELL: I can tell you exactly what
25 was read into the record.

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1 MR. SLATER: Hey, I take your word for it.

2 It's okay. I'm not trying to stop you.

3 MR. SHERIDAN: T-858?

4 MR. SNELL: It's the -- it's one Adam

5 marked, 858. It's been around for a long time.

6 MR. SLATER: Oh, it's -- it's been around.

7 MR. SNELL: Yeah.

8 MR. SLATER: That's all right. I've got

9 my outline here.

10 MR. SNELL: Yeah.

11 MR. SLATER: Yeah, I showed it to him.

12 Page 137, Line 11.

13 I'm not doubting you. Never would.

14 MR. SNELL: I have you -- somebody showed
15 him the front too but, anyhow, I just have a question
16 about Table 2.

17 BY MR. SNELL:

18 Q. Doctor, I've handed you the Altman study,
19 and I'm asking you just to look at Table 2, which
20 reports the anatomic and subjective results, to
21 refresh your memory.

22 A. Yes. Uh-huh.

23 Q. And how did Prolift compare to the
24 anterior colporrhaphy on the primary end point?

25 A. At one year.

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1 Q. At one year.

2 A. At one year.

3 Colporrhaphy group, which is a non-mesh
4 repair, success was 34.5 percent and the mesh repair
5 group, 60.8 percent.

6 Q. How did the Prolift compare in the Altman
7 study of one year to colporrhaphy on the anatomic
8 improvement of prolapse?

9 A. At 12 months, colporrhaphy, 47.5 percent,
10 and mesh repair group, 82.3 percent.

11 Q. How did the Prolift compare to the
12 colporrhaphy at 12 months in the Altman study with
13 regard to whether the women had a sensation of a
14 bulge?

15 A. Colporrhaphy group, 62.1 percent, and mesh
16 repair group, 75.4 percent, meaning absence of
17 sensation, I guess.

18 Q. Okay. And was that significant?

19 A. Yes.

20 MR. SLATER: Objection.

21 BY MR. SNELL:

22 Q. So in the mesh group, the Prolift group,
23 more women had an absence of a sense of a bulge
24 compared to colporrhaphy; is that correct or not?

25 MR. SLATER: Objection.

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1 THE WITNESS: Correct.

2 BY MR. SNELL:

3 Q. Was that result statistically significant?

4 A. Yes.

5 MR. SLATER: Objection.

6 BY MR. SNELL:

7 Q. Plaintiffs' counsel -- do you have
8 Exhibit -- that's all I have on that. Actually, I
9 have one other question.

10 Plaintiffs' counsel, I believe, asked you
11 about whether you were aware if there was a
12 correction published in The New England Journal of
13 Medicine regarding the Altman study?

14 Do you recall that?

15 A. Yes.

16 Q. Do you know whether or not there was a
17 correction?

18 A. My understanding is yes.

19 Q. Okay. And what is your understanding of
20 the extent of the correction issue?

21 MR. SLATER: Objection.

22 THE WITNESS: So I believe it was related
23 to referencing the fact or acknowledging --
24 acknowledging the fact that -- that the -- we weren't
25 the sponsor, we weren't the regulatory sponsor,

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1 because it was an IIS, but the company had visibility
2 to the data and the manuscript and had comments.

3 BY MR. SNELL:

4 Q. Okay.

5 A. I think that's what I remember.

6 Q. And do you recall if The New England
7 Journal made any changes to the data in the study --

8 A. Not to my knowledge.

9 Q. -- as opposed to changing the disclosure
10 that Ethicon had some visibility to the study and had
11 provided comments?

12 A. Not that I recall.

13 Q. Okay. Exhibit 1324 is a committee
14 opinion, December 2011, by the American College of
15 Obstetricians and Gynecologists that plaintiffs'
16 counsel showed you.

17 Do you have a copy --

18 A. I don't think so.

19 Q. -- of that?

20 MR. SLATER: Do you have copies of these?
21 I'm going off memory. And you know what? Also, it
22 would save me time later if you can -- if you're done
23 with the Altman article, if you can give it to me so
24 I can prep my follow-up questioning.

25 MR. SNELL: Okay.

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1 Do you have Altman?

2 MR. SHERIDAN: I think he just flipped it
3 over on the stack.

4 MR. SNELL: No. This is my Altman.

5 MR. SHERIDAN: He was using it.

6 MR. SNELL: That's what I said, I'm going
7 to give him my copy of Table 2. I'll go get somebody
8 to print it out.

9 MR. SLATER: You actually think your
10 highlighting is going to be a big assistance to me?

11 MR. SNELL: No, I don't think so. Oh.
12 Oh. I see what you're saying. No. No. No. I
13 thought you meant --

14 MR. SLATER: Most likely, I'm going to ask
15 you about something he didn't highlight. The odds
16 are.

17 MR. SNELL: Well, then give me that back
18 if you're going to go there. I thought we'd be
19 gentlemen on that.

20 MR. SLATER: We are gentlemen.

21 MR. SNELL: I'll go get you -- I'll go --

22 MR. SLATER: It has nothing to do with the
23 highlighting. I know what I'm looking for. I just
24 want to find the right section --

25 MR. SNELL: Okay.

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1 MR. SLATER: -- to save time. If you
2 don't want me to do it, I'm --

3 MR. SNELL: No. No.

4 MR. SLATER: I could write your -- I could
5 write your Direct.

6 MR. SNELL: We're going to have this
7 issue, though. I mean --

8 MR. SLATER: Off the record.
9 Do you have a lot more to go?

10 MR. SNELL: Huh?

11 MR. SLATER: Do you have a lot more
12 documents to go?

13 MR. SNELL: A few, not many.

14 MR. SLATER: So you're like another 20
15 minutes to a half hour.

16 MR. SNELL: We're off the record.
17 Let's go off the record.

18 VIDEO OPERATOR: The time is now 5:52.
19 This is the end of Disk Number 4.
20 We're going off the record.

21 (Recess, 5:52-6:12 p.m.)

22 VIDEO OPERATOR: The time is now 6:12.
23 This is the beginning of Disk Number 5.
24 We are back on the record.

25 BY MR. SNELL:

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1 Q. Dr. Hart, I've handed you Exhibit T-1323,
2 which was marked earlier in your deposition. It is
3 Dr. Piet Hinoul's benefit-risk profile of
4 transvaginal mesh products.

5 MR. SLATER: Which exhibit do you want
6 now? I thought you were doing the other thing. I
7 guess you --

8 MR. SNELL: I'm going to -- I'm going to
9 go here, then there. So 1323.

10 MR. SLATER: Is this in this pile?

11 MR. SNELL: No. It's in the earlier pile
12 I gave you.

13 MR. SLATER: What earlier pile?

14 MR. SNELL: When I gave you the copy of
15 the FDA 2011. That's the mesh part. Look at the
16 back of that. It's Piet's risk-benefit analysis from
17 2012.

18 MR. SLATER: It's attached. Let me just
19 get it out.

20 All right. Sorry about that.

21 MR. SNELL: Oh, no problem. Do it again.

22 BY MR. SNELL:

23 Q. Dr. Hart, I've handed you Exhibit T-1323,
24 which was marked earlier in your deposition, the June
25 2012 benefit-risk profile of transvaginal mesh

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1 products used for the treatment of pelvic organ
2 prolapse by Piet Hinoul.

3 Do you have that in front of you?

4 A. I do, yes.

5 Q. And what is this document?

6 A. This -- I believe this was a document that
7 was used and provided to the MHRA, one of the
8 European health authorities, when discussing the
9 benefit-risk profile for these -- these products.

10 Q. On Page 3, the first paragraph under
11 summary, the fifth line down says that Ethicon,
12 Inc.'s review by medical affairs has confirmed that
13 the evidence demonstrates an acceptable benefit-risk
14 profile for these products when placed in
15 appropriately selected patients by experienced
16 surgeons.

17 Did I read that correctly?

18 MR. SLATER: Objection.

19 THE WITNESS: Yes.

20 BY MR. SNELL:

21 Q. Had Ethicon Women's Health medical affairs
22 group done a benefit-risk analysis in 2012 on its
23 prolapse products?

24 A. Yes.

25 Q. Did Ethicon Women's Health & Urology do a

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1 benefit-risk assessment on its stress urinary
2 incontinence products in 2012?

3 A. Yes.

4 Q. And what were the determinations from
5 those benefit-risk analyses?

6 A. There was continued evidence that supported
7 a -- a -- an appropriate and positive benefit-risk
8 profile for the products, similar to the others that
9 we discussed.

10 Q. Now, I believe you were asked a question
11 earlier in your deposition about whether
12 reasonable -- reasonable opinions could differ that
13 Prolift should be on the market.

14 Do you recall a question similar to that?

15 MR. SLATER: Objection to the form.

16 THE WITNESS: I -- I recall a question
17 similar to that. I didn't -- I don't remember it
18 being should the product be on the market but...

19 BY MR. SNELL:

20 Q. Would it be a reasonable opinion that
21 Prolift -- strike that.

22 Based on everything you've seen in all the
23 risk assessments, would you think it would be a
24 reasonable opinion that Prolift should not have been
25 brought to the market, based on its safety profile?

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1 MR. SLATER: Objection.

2 THE WITNESS: No.

3 BY MR. SNELL:

4 Q. Now, can surgeons choose whether or not to
5 use a mesh product?

6 A. Yes. Sure.

7 Q. Is that totally within the surgeon's
8 discretion?

9 A. Yes.

10 MR. SLATER: Objection, belated. And I'll
11 tell you the basis of it: The doctor doesn't decide
12 100 percent what happens. The patient also has
13 input.

14 BY MR. SNELL:

15 Q. Dr. Hinoul's 2012 risk-benefit analysis at
16 Page 5 references, among other things, the American
17 College of Obstetricians and Gynecologists and the
18 American Urogynecologic Society; correct?

19 It's on Page 5 in the conclusions section
20 plaintiffs' counsel pointed you to.

21 A. Yes.

22 Q. If you turn to the next page, Page 6, what
23 are these studies in Table 1?

24 A. The title says randomized, controlled
25 trials comparing polypropylene mesh to traditional

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1 native vaginal tissue repairs.

2 Q. And what, overall, is your impression from
3 Table 1 as to how polypropylene mesh compares to
4 traditional native vaginal tissue repairs?

5 MR. SLATER: Objection to the form.

6 THE WITNESS: Well, it -- you know, if you
7 go down column anatomic cure for mesh versus anatomic
8 cure for traditional, in each instance the results
9 were in favor of cure with mesh as compared to
10 traditional methods and at least all but one appear
11 to be statistically significant.

12 BY MR. SNELL:

13 Q. The one that wasn't was the Sokol paper
14 that we've discussed earlier?

15 A. Yes.

16 Q. And is that -- do you know whether or not
17 that has anything to do with the small number of
18 patients in the Sokol study?

19 MR. SLATER: Objection.

20 THE WITNESS: Well, it is a small number
21 of patients in that study and that limits its power
22 to detect a significant difference.

23 MR. SNELL: Okay.

24 BY MR. SNELL:

25 Q. I'd like you to look at Exhibit T-1324,

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1 which plaintiffs' counsel pointed you toward earlier
2 in your deposition.

3 MR. SHERIDAN: It's not me.

4 MR. SNELL: I know.

5 THE WITNESS: Not me.

6 MR. SNELL: Sounds like some phone in the
7 wall.

8 VIDEO OPERATOR: Might be outside in the
9 hallway.

10 BY MR. SNELL:

11 Q. Doctor, do you have in front of you
12 Exhibit T-1324, the December 2011, committee opinion
13 that plaintiffs' counsel marked earlier in your
14 deposition?

15 A. Yes.

16 Q. And do you recall plaintiffs' counsel had
17 you read one of the bullet points on Page 5 that
18 discussed pelvic organ prolapse, vaginal mesh repair
19 should be reserved for high-risk individuals?

20 MR. SLATER: Objection.

21 BY MR. SNELL:

22 Q. Do you recall plaintiffs' counsel asking
23 you to read that or not?

24 A. I remember -- yeah, I remember that
25 question.

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1 Q. I'd like to ask you about a couple other
2 things.

3 First of all, on the front page --

4 MR. SLATER: So now we're not on Page 5
5 anymore? We're on the front page now?

6 MR. SNELL: Yeah. But it pertains to Page
7 5.

8 BY MR. SNELL:

9 Q. It says in the top, the information should
10 not be construed as dictating an exclusive course of
11 treatment or procedure to be followed.

12 Did I read that correctly?

13 MR. SLATER: Objection.

14 THE WITNESS: You did.

15 BY MR. SNELL:

16 Q. That wasn't something plaintiffs' counsel
17 had you read earlier; correct?

18 MR. SLATER: Objection.

19 THE WITNESS: Not that I recall.

20 BY MR. SNELL:

21 Q. Turn to the third page, the bottom left
22 column. It says, pelvic pain, groin pain and
23 dyspareunia can occur with pelvic reconstructive
24 surgery regardless of the use or non-use of mesh.

25 Did I read that correctly?

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1 MR. SLATER: Objection.

2 THE WITNESS: You did.

3 BY MR. SNELL:

4 Q. Do you have an understanding as to whether
5 dyspareunia can occur with pelvic reconstructive
6 surgery regardless of the use or non-use of mesh?

7 MR. SLATER: Objection.

8 THE WITNESS: Yes.

9 BY MR. SNELL:

10 Q. What is your understanding?

11 A. Well, that -- that pelvic reconstructive
12 surgery with or without the use of mesh could result
13 in pelvic pain or dyspareunia.

14 Q. It says, however, a complication unique to
15 mesh is erosion, also described as exposure or
16 extrusion; correct?

17 A. Yes.

18 Q. And had Ethicon warned of the risk of mesh
19 exposure with its products?

20 MR. SLATER: Objection.

21 THE WITNESS: Yes.

22 BY MR. SNELL:

23 Q. Is the risk of mesh exposure a risk that
24 would be known to the types of surgeons for whom the
25 mesh products would be used?

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1 MR. SLATER: Objection.

2 THE WITNESS: Yes.

3 BY MR. SNELL:

4 Q. I believe plaintiffs' counsel asked you a
5 question earlier today about mesh being used in the
6 pelvic space in or around the time of 1998 and I
7 believe your testimony was, obviously, that there had
8 been some usage for the TVT mesh; is that correct?

9 MR. SLATER: Objection. Not only do I
10 object to the question, the entire line, because of
11 the way that it's being introduced in such a leading
12 fashion, so any testimony on this line, I object to
13 the entire line.

14 MR. SNELL: How about this?

15 MR. SLATER: Do what you want --

16 MR. SNELL: Well, that's what he's
17 testified to.

18 BY MR. SNELL:

19 Q. Was the TVT mesh used in the 1990s?

20 A. Yes.

21 Q. All right. Do you know if mesh was used
22 in abdominal sacrocolpopexy in the 1990s --

23 A. Yes.

24 Q. -- in the pelvic space?

25 A. Yes.

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1 Q. And would that be information that
2 urogynecologists would know of?

3 MR. SLATER: Objection.

4 THE WITNESS: Yes.

5 BY MR. SNELL:

6 Q. Would that be information that urologists
7 focusing on pelvic reconstructive medicine would know
8 of?

9 MR. SLATER: Objection.

10 THE WITNESS: Yes.

11 BY MR. SNELL:

12 Q. Do you have Exhibit 409?

13 A. 409?

14 Q. Yes.

15 MR. SLATER: Do you know what it is?

16 MR. SNELL: I think it was --

17 THE WITNESS: What does it look like?

18 MR. SLATER: Did we get gypped at the
19 drive-through?

20 MR. SNELL: What's that?

21 MR. SLATER: I said, did we get gypped at
22 the drive-through?

23 MR. SNELL: Oh, my God.

24 You don't have it?

25 MR. SLATER: I don't think so.

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1 MR. SNELL: Adam, do they have --

2 VIDEO OPERATOR: The time is now 6:26.

3 We're going off the record.

4 (Recess, 6:26-6:31 p.m.)

5 VIDEO OPERATOR: The time is now 6:31.

6 This is -- we are back on the record.

7 BY MR. SNELL:

8 Q. Dr. Hart, do you have Exhibit 1344 --

9 A. Don't know.

10 Q. -- the TVT instructions for use that
11 plaintiffs' counsel marked with you earlier today?

12 A. Yes.

13 Q. Turn to the first page, if you would.

14 Under "Important," it says, the device should be used
15 only by physicians trained in the surgical treatment
16 of stress urinary incontinence and specifically in
17 implanting the Gynecare TVT device.

18 Did I read that correctly?

19 MR. SLATER: Objection.

20 THE WITNESS: Yes.

21 BY MR. SNELL:

22 Q. It also states, these instructions are
23 recommended for general use of the device.

24 Variations in use may occur in specific procedures
25 due to the individual technique and patient anatomy.

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1 Did I read that correctly?

2 MR. SLATER: Objection.

3 THE WITNESS: Yes.

4 BY MR. SNELL:

5 Q. Now, plaintiffs' counsel asked you
6 questions about the use of TVT -- strike that.

7 Plaintiffs' counsel asked you questions
8 about the implantation of TVT under local as compared
9 to regional or general anesthesia.

10 Do you recall those questions?

11 A. Yes.

12 Q. Turn to the very next page in the
13 instructions for use.

14 Number 1, what does that state?

15 A. The procedure can be carried out under
16 local anesthesia but it can also be performed using
17 regional or general anesthesia.

18 Q. Did professional education on the TVT
19 discuss the different types of anesthesia use?

20 MR. SLATER: Objection.

21 MR. SHERIDAN: Objection.

22 THE WITNESS: Yes.

23 BY MR. SNELL:

24 Q. Do you know whether or not the TVT
25 surgeons' monograph discussed the different types of

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1 anesthesia for TVT?

2 MR. SLATER: Objection.

3 THE WITNESS: I do.

4 BY MR. SNELL:

5 Q. And was it discussed?

6 A. Yes.

7 MR. SLATER: Objection.

8 That was too quick for me to object in
9 between.

10 BY MR. SNELL:

11 Q. Now, I believe in response to plaintiffs'
12 counsel's questions about this you mentioned wanting
13 to see or your answers depending upon level-one
14 evidence?

15 MR. SLATER: Objection.

16 THE WITNESS: That was in a hypothetical
17 for instance. Yes.

18 BY MR. SNELL:

19 Q. What is level-one evidence?

20 A. So it would be considered the highest
21 evidence available upon which in an evidence-based
22 medicine sort of practice philosophy would be
23 considered the highest-level evidence to help guide
24 surgeons in -- in -- in decision-making.

25 Q. Plaintiffs' counsel asked you

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1 hypotheticals pertaining to the claim that TVT
2 implanted via local anesthesia would be 10 to 15
3 percent more efficacious than otherwise.

4 My question to you is, did plaintiffs'
5 counsel show you in any significant number of the
6 over 100 RCTs for TVT that you earlier testified to
7 which actually demonstrate that there is a
8 significant difference for TVT's efficacy depending
9 upon the anesthesia used?

10 MR. SLATER: Objection.

11 THE WITNESS: No.

12 BY MR. SNELL:

13 Q. Do you know whether the types of surgeons,
14 as mentioned on the first page, those trained in
15 surgical treatment of stress urinary incontinence,
16 would have experience using regional anesthesia?

17 MR. SHERIDAN: Objection.

18 MR. SLATER: Objection.

19 THE WITNESS: Yes.

20 BY MR. SNELL:

21 Q. And would they?

22 A. Yes, they would.

23 MR. SLATER: Objection.

24 BY MR. SNELL:

25 Q. And the types of surgeons mentioned on the

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1 first page of the IFU, those trained in the surgical
2 treatment of stress urinary incontinence, would they
3 have experience using general anesthesia?

4 MR. SLATER: Objection.

5 THE WITNESS: Yes.

6 MR. SLATER: You've got to read faster,
7 dude.

8 MR. SHERIDAN: I read too slowly.

9 MR. SLATER: No, no one touches my phone.
10 I don't want your germs. Coughing in your hand
11 before, for the record.

12 MR. SHERIDAN: Okay.

13 BY MR. SNELL:

14 Q. The evidence that you're aware of, do you
15 believe anything that should be in the IFU about any
16 alleged decrease in efficacy if the TVT is not placed
17 via local anesthesia?

18 MR. SLATER: Objection.

19 THE WITNESS: Not evidence that I'm aware
20 of, no.

21 BY MR. SNELL:

22 Q. Do you know whether surgeons can work with
23 anesthesiologists to time anesthesia such that a
24 patient can be responsive during a surgery?

25 MR. SLATER: Objection.

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1 THE WITNESS: Yes.

2 BY MR. SNELL:

3 Q. Do you recall that being discussed in the
4 surgeons' monograph?

5 A. It is.

6 MR. SLATER: Objection.

7 BY MR. SNELL:

8 Q. Do you recall it being discussed in the
9 professional education for TVT?

10 MR. SLATER: Objection.

11 THE WITNESS: Yes.

12 BY MR. SNELL:

13 Q. Plaintiffs' counsel showed you some
14 different sales aids regarding TVT and TVT-O and
15 TVT-Secur today; correct?

16 A. Correct.

17 Q. I have just a few questions about them.

18 Turn to Exhibit 1350, "Gynecare TVT Family
19 of Products, Tension-Free Support For Incontinence."

20 A. Okay.

21 Q. You were asked some questions about the
22 first page, particularly the third bullet point about
23 the clinical study in an average of 11.5 years.

24 Do you recall those questions?

25 A. Yes.

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1 Q. If a surgeon wants to read those studies,
2 can he or she read them?

3 MR. SLATER: Objection.

4 THE WITNESS: Yes.

5 BY MR. SNELL:

6 Q. Plaintiffs' counsel asked you about the
7 fact that there was not a single case of tissue
8 reaction, as mentioned on the third bullet point.

9 Do you recall that?

10 A. Yes.

11 MR. SLATER: Objection.

12 BY MR. SNELL:

13 Q. Do you believe that Ethicon is saying in
14 that bullet point that there's no foreign body
15 reaction with TVT?

16 A. No.

17 MR. SLATER: Objection.

18 BY MR. SNELL:

19 Q. What is your interpretation of that bullet
20 point?

21 A. I would interpret it as to mean in this
22 particular clinical study the investigators or the
23 reporters did not report a single -- as it says, a
24 single case of tape erosion, tissue reactions or
25 other adverse effects on the tape were found, and to

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1 me that would imply adverse tissue reaction of some
2 sort that led to a clinically significant outcome if
3 I -- you know, if I read this as a surgeon.

4 Q. And this was the Nilsson 11.5-year study?

5 A. Yes.

6 Q. Do you know whether or not there are other
7 studies that are ten years of duration or longer on
8 TVT?

9 A. Yes.

10 Q. And what is your opinion with regard to
11 the consistency, if any, of those studies --

12 A. Well, I --

13 MR. SLATER: Objection.

14 THE WITNESS: You know, my --

15 BY MR. SNELL:

16 Q. -- to the Nilsson 11-year, 11.5-year
17 study?

18 MR. SLATER: Still object.

19 THE WITNESS: My -- my assessment and
20 my -- my knowledge is that they're broadly
21 consistent.

22 BY MR. SNELL:

23 Q. Turn to Exhibit 243.

24 MR. SHERIDAN: Was that one used today?

25 MR. SNELL: Yes.

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1 THE WITNESS: Got it.

2 BY MR. SNELL:

3 Q. The Prolift+M sales aid.

4 A. Okay.

5 Q. Let me ask you, what is medical affairs'
6 role in reviewing these sales aids, if any?

7 A. So as part of the copy approval
8 cross-functional team, they would review their --
9 their -- they do review the pieces and their input
10 would be with regard, obviously, to, from a medical
11 standpoint, that the -- that the information
12 presented is -- is scientifically accurate and fair
13 and balanced. That's a high level.

14 Q. Okay. Are surgeons trained that there is
15 a foreign body reaction whenever you put a foreign
16 body in during their medical school or surgical
17 training?

18 MR. SLATER: Objection.

19 THE WITNESS: Yes.

20 BY MR. SNELL:

21 Q. When -- when is that type of training --
22 strike that.

23 When is the foreign body response covered
24 with surgeons during their medical school or later
25 training?

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1 MR. SLATER: Objection.

2 THE WITNESS: Well, when they're in
3 medical school, they're not surgeons yet and may
4 not -- may or may not know that they want to be
5 surgeons at that stage, but during their pathology
6 courses or even during their surgery rotations,
7 they -- they would have that kind of training.

8 MR. SNELL: Okay.

9 THE WITNESS: And then subsequent, if
10 you -- if you go into surgical training, same thing,
11 you would -- you would have ongoing training and
12 understanding about the tissue response or foreign
13 body reaction to implanted materials.

14 BY MR. SNELL:

15 Q. Turn to Exhibit 1347, the TVT.

16 A. Saw that recently.

17 MR. SLATER: What have you got there?

18 MR. SNELL: 1347, the TVT.

19 MR. SLATER: I've got it.

20 MR. SNELL: 2002 copyright.

21 BY MR. SNELL:

22 Q. So, Dr. Hart, do you have in front of you
23 Exhibit T-134 -- strike that.

24 Dr. Hart, do you have in front of you
25 Exhibit T-1347, the 2002 copyright Gynecare TVT?

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1 A. Yes.

2 Q. This was an exhibit marked earlier today
3 in your deposition; correct?

4 A. Yes.

5 Q. The second page there is the first section
6 that plaintiffs' counsel pointed you to about the
7 cured/improved success rates in studies evaluating 50
8 or more patients.

9 Do you recall that?

10 A. Yeah. Yes.

11 Q. The first two studies are by Professor
12 Ulmsten, as plaintiffs' counsel pointed out; correct?

13 A. Correct.

14 Q. But are there other studies besides Dr.
15 Ulmsten?

16 MR. SLATER: Objection.

17 THE WITNESS: Yes.

18 BY MR. SNELL:

19 Q. Are there numerous other studies besides
20 Dr. Ulmsten?

21 MR. SLATER: Objection.

22 THE WITNESS: Nine others that I count.

23 BY MR. SNELL:

24 Q. And are those studies by surgeons,
25 physicians other than Dr. Ulmsten consistent or

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1 inconsistent with the results of Dr. Ulmsten's
2 studies?

3 MR. SLATER: Objection.

4 THE WITNESS: Consistent with the Ulmsten
5 studies.

6 BY MR. SNELL:

7 Q. And based on your review of additional
8 literature, including, as you testified to,
9 additional ten-plus-year studies with TVT, are these
10 data consistent or inconsistent with Dr. Ulmsten's
11 results for the TVT as to its ability to either cure
12 or improve a woman's stress urinary incontinence?

13 A. Yeah.

14 MR. SLATER: Objection to the form.

15 THE WITNESS: Yeah, I believe that my
16 recollection is that they are consistent.

17 BY MR. SNELL:

18 Q. Now, Professor Ulmsten was one of the ones
19 who came up with the TVT concept; correct?

20 A. That -- my understanding, yes.

21 Q. And there's peer-review papers about
22 Professor Ulmsten and his involvement with TVT;
23 correct?

24 MR. SLATER: Objection.

25 THE WITNESS: What do you mean there? Say

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1 that again?

2 MR. SNELL: Sure thing.

3 BY MR. SNELL:

4 Q. There are publications concerning
5 Doctor -- Professor Ulmsten and his use of the TVT.

6 A. Well, there are publications wherein he
7 describes these, yes. Is that what you're asking?

8 Q. Right. Yeah.

9 A. Yes.

10 Q. And the TVT is an Ethicon product;
11 correct?

12 A. Correct.

13 Q. Would surgeons, the types of whom who
14 would use TVT, pelvic floor surgeons, would they know
15 that Professor Ulmsten was involved in the TVT
16 development?

17 MR. SLATER: Objection.

18 THE WITNESS: I would expect so.

19 BY MR. SNELL:

20 Q. One of the papers in the 510(k) that
21 plaintiffs' counsel pointed to earlier discussed how
22 Professor Ulmsten tried different meshes before he
23 began trying Prolene mesh in the TVT; correct?

24 A. Correct.

25 MR. SLATER: Objection.

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1 BY MR. SNELL:

2 Q. On the third page of the 2002 pamphlet
3 plaintiffs' counsel asked you about the bullet point
4 where it says, no foreign body reaction after Prolene
5 mesh implantation.

6 Do you recall that?

7 A. Yeah.

8 Q. Now, what is your interpretation of what
9 that statement means, as a surgeon?

10 A. Well, it references --

11 MR. SLATER: Objection.

12 THE WITNESS: It references or it cites a
13 Citation Number 22 that I'm not familiar with,
14 "Influence on Differing Sling Materials on Connective
15 Tissue Metabolism in Stress Urinary Incontinent
16 Women," and I don't have familiarity with that
17 publication, but it obviously is referring to some
18 statements that were made in -- in that publication.

19 BY MR. SNELL:

20 Q. What's the significance, if any, of the
21 citations to different articles and studies in these
22 sales aids?

23 MR. SLATER: Objection.

24 THE WITNESS: They would form the basis by
25 which statements would be made.

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1 BY MR. SNELL:

2 Q. Is Ethicon saying that there's no foreign
3 body reaction with Prolene mesh?

4 A. No. They're -- they're stating that --
5 that a Publication Number 22 indicates, however they
6 define it, no foreign body reaction to Prolene mesh
7 implantation.

8 Q. And as a surgeon, how would you interpret
9 that?

10 A. I would go read the article.

11 MR. SLATER: Objection.

12 THE WITNESS: I would go read the article.
13 As a surgeon, knowing that there is some foreign body
14 reaction to an implant, I would want to know, what
15 are they referring to.

16 BY MR. SNELL:

17 Q. Turn to Exhibit 1348. It's another sales
18 aid referenced today regarding TVT.

19 Are you there?

20 A. Yeah.

21 Q. Okay. It talks about the success of
22 Gynecare TVT has been proven in multiple studies
23 evaluating 50 or more patients and it cites to
24 footnotes -- I'm sorry -- References 2 to 12; is that
25 correct?

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1 A. That's correct.

2 MR. SLATER: Objection.

3 BY MR. SNELL:

4 Q. And are all of those references studies by
5 Professor Ulmsten?

6 A. I don't think so, no.

7 Q. It states, more clinical data than any
8 other mid-urethral sling device; correct?

9 A. Correct.

10 Q. Do you know whether or not that's a
11 correct statement?

12 MR. SLATER: Objection.

13 THE WITNESS: It's my -- yeah, it's -- it
14 is my understanding that there's -- there's more
15 literature on the use of this device than others.

16 MR. SLATER: Just for the record, I had
17 intended to but did not object to the question before
18 that, again, on the form.

19 BY MR. SNELL:

20 Q. Turn back to the page that says, only
21 Gynecare TVT uses Prolene polypropylene mesh.

22 A. Okay.

23 Q. Do you recall plaintiffs' counsel asked
24 you questions about this page, particularly at the
25 bottom, the statement by --

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1 A. Yes.

2 Q. -- Nilsson?

3 A. Yes.

4 MR. SLATER: Objection.

5 BY MR. SNELL:

6 Q. Nilsson writes, the TVT procedure seems to
7 result in good long-term cure with cure rates similar
8 to the best traditional operations.

9 Did I read that correctly?

10 MR. SLATER: Objection.

11 THE WITNESS: Yes.

12 BY MR. SNELL:

13 Q. This is something plaintiffs' counsel
14 asked you about; correct?

15 A. Correct.

16 Q. Based on your review and analyses, do you
17 agree or disagree with that statement by Professor
18 Nilsson?

19 MR. SLATER: Objection.

20 THE WITNESS: I agree.

21 BY MR. SNELL:

22 Q. Turn to Exhibit 1349. It's another sales
23 aid referenced by plaintiffs' counsel.

24 On the -- this is a document that
25 plaintiffs' counsel asked you about today; correct?

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1 A. Yes.

2 Q. Did the TVT-Secur use the same mesh as the
3 TVT and TVT transobturator?

4 MR. SLATER: Objection.

5 THE WITNESS: To my knowledge, yes.

6 MR. SNELL: Okay.

7 BY MR. SNELL:

8 Q. Turn to the first page. It says, the
9 Gynecare TVT family of products has the most
10 level-one evidence of any mid-urethral sling and has
11 treated over 1.5 million patients.

12 Did I read that correctly?

13 MR. SLATER: Objection.

14 THE WITNESS: You did.

15 BY MR. SNELL:

16 Q. And as plaintiffs' counsel pointed out,
17 this was copy written back in 2009; correct?

18 A. Well, I don't remember that.

19 Q. At the very last page, the small print.

20 A. Oh, this small print, yeah.

21 Yes, that's right.

22 Q. Is that statement that we read about the
23 TVT family of products having the most level-one
24 evidence consistent or inconsistent with your
25 knowledge?

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1 MR. SLATER: Objection.

2 THE WITNESS: Consistent.

3 BY MR. SNELL:

4 Q. And the sling has treated over 1.5 million
5 patients, is that consistent or inconsistent with
6 your knowledge?

7 MR. SLATER: Objection.

8 THE WITNESS: Consistent.

9 MR. SLATER: All right. Listen, I've got
10 to know what your plan is because I'm ready to go to
11 dinner. It's 7:00 at night. We ate lunch at 12:30.

12 MR. SNELL: Do you want to break for
13 dinner?

14 MR. SLATER: No. Listen. Listen.

15 MR. SNELL: I don't know --

16 VIDEO OPERATOR: Do you want to go off the
17 record?

18 MR. SLATER: You can go off the video, you
19 can go off the record. I don't care.

20 VIDEO OPERATOR: Time is now 6:55.

21 We're going off the record.

22 (Recess, 6:55-7:01 p.m.)

23 VIDEO OPERATOR: The time is now 7:01.

24 This is the -- we are back on the record.

25 BY MR. SNELL:

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1 Q. Dr. Hart, on the first day of your
2 deposition you were asked some questions about
3 polypropylene mesh and cancer.

4 Do you, in general, recall covering that
5 subject?

6 A. We -- yes.

7 Q. Based on everything you've seen, have you
8 seen any substantial evidence demonstrating a causal
9 relationship between polypropylene mesh and cancer?

10 MR. SLATER: Objection.

11 THE WITNESS: No.

12 BY MR. SNELL:

13 Q. Take a look at Exhibit T-1303, a paper
14 marked by plaintiffs' counsel by Birolini.

15 A. Don't know that I have it.

16 MR. SNELL: A copy of that one.

17 THE WITNESS: Okay.

18 BY MR. SNELL:

19 Q. Now, these are two case reports; is that
20 correct or not?

21 A. That's correct.

22 Q. Are case reports clinical studies?

23 MR. SLATER: Objection.

24 THE WITNESS: I didn't -- I didn't --

25 BY MR. SNELL:

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1 Q. Are case reports clinical studies?

2 A. No.

3 Q. What is anecdotal evidence?

4 A. That just means sort of almost, I guess,
5 word of mouth. A physician or a scientist would --
6 would provide information regarding observations that
7 he or she would make -- had made outside of a
8 clinical study.

9 Q. Are these case reports anecdotal evidence?

10 A. They're anecdotal, for sure, yes.

11 Q. Now --

12 MR. SLATER: Objection.

13 BY MR. SNELL:

14 Q. -- did these --

15 MR. SLATER: I just want you to know, it
16 went quicker, I'm objecting to the question.

17 MR. SNELL: Okay.

18 MR. SLATER: So you know that, for the
19 record.

20 BY MR. SNELL:

21 Q. Now, did these two case reports concern
22 polypropylene mesh?

23 A. No.

24 Q. What type of mesh had been implanted in
25 these two case reports?

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1 A. As I recall, polyester, but let me be sure.

2 Q. On the third page above Figure 5 it talks
3 about exposed pieces of polyester mesh.

4 Do you see that in the first column on the
5 left?

6 MR. SLATER: Objection.

7 THE WITNESS: Yes.

8 BY MR. SNELL:

9 Q. Case 2 on the right side of that same
10 page, that person developed an incisional hernia that
11 was treated with polyester mesh reinforcement.

12 Did I read that correctly?

13 A. Yes.

14 Q. Is polyester the same as polypropylene?

15 A. No.

16 Q. If you turn to the last page, the
17 discussion, can you read the second sentence that
18 begins, in both patients?

19 A. Yeah. In both patients the infection took
20 place over a bridged polyester mesh that got infected
21 and unincorporated. It is -- oh, that's the
22 sentence.

23 Q. That's fine.

24 And it goes on to say, it is our
25 impression that the mesh itself did not clearly --

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1 did clearly not cause it.

2 Did I read that correctly?

3 MR. SLATER: Objection.

4 THE WITNESS: You did.

5 BY MR. SNELL:

6 Q. So this isn't even a case report about
7 polypropylene mesh and cancer. This was about
8 polyester mesh and cancer.

9 MR. SLATER: Objection.

10 BY MR. SNELL:

11 Q. Is that correct or not?

12 A. Correct.

13 Q. Actually, what type of mesh did these
14 surgeons turn to to repair the defects after the
15 cancer was discovered?

16 A. Polypropylene.

17 Q. At the bottom of that page it says, a
18 heavyweight, large-pore onlay polypropylene mesh was
19 used to reinforce a primary closure of the midline in
20 this patient.

21 Did I read that correctly?

22 MR. SLATER: Objection.

23 THE WITNESS: Yes.

24 BY MR. SNELL:

25 Q. The big gap after tumor resection in Case

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1 2 required the use of Proceed mesh to bridge the
2 resulting defect.

3 Did I read that correctly?

4 MR. SLATER: Objection.

5 THE WITNESS: Yes.

6 BY MR. SNELL:

7 Q. The next paragraph at the bottom says, we
8 strongly recommend a single-stage operation with
9 removal of the infected mesh, primary restoration of
10 the midline and onlay reinforcement with
11 polypropylene mesh in such patients.

12 Did I read this correctly --

13 MR. SLATER: Objection.

14 BY MR. SNELL:

15 Q. -- in the study plaintiffs' counsel showed
16 you?

17 A. You did.

18 MR. SLATER: Hey, let me ask you, what's
19 your point? It's a case report that's anecdotal,
20 that nobody should look to, or are you saying it's an
21 important study, that everyone should listen to it.
22 Make up your mind, man.

23 MR. SNELL: What do you mean?

24 MR. SLATER: You're all over the place.
25 Make up your mind. Make a point.

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1 MR. SNELL: I did.

2 MR. SLATER: You're just scattering
3 shotgun pellets all over the field. You're not
4 hitting anything.

5 MR. SNELL: Okay. Okay.

6 BY MR. SNELL:

7 Q. Based on everything you've seen as -- was
8 there any need for Ethicon to warn about a alleged
9 association with cancer?

10 MR. SLATER: Objection.

11 THE WITNESS: No.

12 BY MR. SNELL:

13 Q. Exhibit -- let's move to Exhibit 1333.
14 It's the Johnson & Johnson investigator-initiated
15 studies policy plaintiffs' counsel discussed with
16 you.

17 A. Got it.

18 Q. And this was discussed in the context of a
19 study done by Professor Ulmsten back in the 1990s as
20 well?

21 MR. SLATER: Objection.

22 THE WITNESS: Yes.

23 BY MR. SNELL:

24 Q. Turn to Exhibit 1329, the License and
25 Supply Agreement plaintiffs' counsel marked earlier

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1 in your deposition.

2 A. I may not have that.

3 Q. Find it?

4 A. No, not yet. I don't think I saw it.

5 MR. SHERIDAN: It's not in that record.

6 MR. SNELL: I know I -- I thought I gave
7 it to you. I know I gave Adam a copy of it because I
8 used the copy I have for you.

9 Just look through this stack over here.

10 THE WITNESS: Here we go. Is this it?

11 MR. SNELL: Yeah, that's it.

12 THE WITNESS: Yes, I have it. Sorry about
13 that.

14 BY MR. SNELL:

15 Q. You have a huge pile over there. Sorry.
16 Ready?

17 A. Yeah.

18 Q. So you have Exhibit T-1329 in front of
19 you?

20 A. Uh-huh.

21 Q. Correct?

22 A. Correct.

23 Q. Now, what is this document that
24 plaintiffs' counsel marked with you earlier in your
25 deposition?

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1 A. This is a -- as it says here, License and
2 Supply Agreement between two parties, Johnson &
3 Johnson International and Medscand, regarding the
4 acquisition of license and supply by Johnson &
5 Johnson from Medscand.

6 Q. Is this a study contract?

7 A. No.

8 Q. Is this a study agreement?

9 A. No.

10 MR. SLATER: Objection.

11 BY MR. SNELL:

12 Q. Is this a study protocol?

13 A. No.

14 Q. Is this an investigator-initiated study,
15 similar to those referenced in the policy plaintiffs'
16 counsel discussed with you that's been marked as
17 Exhibit T-1333?

18 MR. SLATER: Objection.

19 THE WITNESS: No.

20 BY MR. SNELL:

21 Q. Plaintiffs' counsel -- if you go to Page 7
22 and 8, plaintiffs' counsel mentioned that this was
23 concerning Section 3.6, milestone payments.

24 A. Okay.

25 Q. And I believe plaintiffs' counsel pointed

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1 to Milestone B about the payment of the amount of
2 \$400,000 --

3 MR. SLATER: Objection to the form of the
4 question.

5 BY MR. SNELL:

6 Q. -- concerning the clinical trial as
7 specified in Exhibit C?

8 MR. SLATER: Objection to the form of the
9 question.

10 THE WITNESS: Yes.

11 BY MR. SNELL:

12 Q. And are milestone payments common in the
13 industry in licensing and supply agreements?

14 MR. SLATER: Objection.

15 THE WITNESS: Yes.

16 BY MR. SNELL:

17 Q. And what's your understanding as to --
18 withdrawn.

19 So just to be clear, would this policy
20 that's been marked as Exhibit T-1333 apply to a
21 \$400,000 milestone payment, as reflected in the
22 License and Supply Agreement from 1997?

23 MR. SLATER: Objection.

24 THE WITNESS: No.

25 BY MR. SNELL:

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1 Q. Do you have Exhibit T-1337? It's
2 TVT-Secur --

3 A. I haven't seen that one recently.

4 MR. SHERIDAN: 1317?

5 MR. SNELL: 1337.

6 MR. SHERIDAN: Okay.

7 THE WITNESS: I said no last time and I
8 was wrong so --

9 MR. SNELL: It looks like this
10 (indicating).

11 THE WITNESS: I'm still saying no.

12 MR. SLATER: What are you looking for?

13 MR. SNELL: 1337.

14 THE WITNESS: I think no is still the
15 answer for this one. I don't have it.

16 MR. SNELL: Did I give you two of those,
17 Adam? Because I made copies of it. Do you have the
18 quality board followup?

19 MR. SLATER: One copy.

20 MR. SNELL: Here. Let me help you.

21 THE WITNESS: There it is, yeah.

22 MR. SNELL: Okay. Yeah, I thought I gave
23 it to you.

24 THE WITNESS: Must be -- I'm sorry.

25 BY MR. SNELL:

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1 Q. Now, we're going; right?

2 A. Yeah.

3 Q. Actually, before we go there, actually, I
4 want to ask you a question.

5 So we were just looking at the License and
6 Supply Agreement regarding TVT from 1997; correct?

7 A. Correct.

8 Q. Is TVT still being marketed today?

9 A. Yes.

10 Q. Plaintiffs' counsel showed you
11 professional organizational statement about mesh for
12 prolapse, correct, from 2011?

13 A. Showed me what?

14 Q. A professional organizational statement
15 regarding prolapsed mesh from December 2011.

16 A. Yeah. Yeah.

17 MR. SLATER: Objection.

18 BY MR. SNELL:

19 Q. Have you seen professional organization
20 statements regarding TVT mesh?

21 MR. SLATER: Objection.

22 THE WITNESS: I believe so.

23 BY MR. SNELL:

24 Q. Have you seen AUGS, the American
25 Urogynecology Association -- strike that.

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1 Have you seen AUGS's, the American
2 Urogynecology Society's, statement regarding TVT?

3 A. Yes.

4 MR. SLATER: Objection.

5 BY MR. SNELL:

6 Q. How is TVT referred to by AUGS?

7 MR. SLATER: Objection.

8 THE WITNESS: I can't quote it verbatim
9 but -- but essentially gold standard kind of
10 language.

11 BY MR. SNELL:

12 Q. Now, have you heard of TVT referred to as
13 the standard of care?

14 A. Yes.

15 MR. SLATER: Objection.

16 BY MR. SNELL:

17 Q. Have you seen a similar statement by the
18 American Urology Association --

19 MR. SLATER: Objection.

20 THE WITNESS: Yes.

21 BY MR. SNELL:

22 Q. -- regarding TVT?

23 Have you seen a similar statement
24 regarding TVT and TVT-O mid-urethral slings as being
25 the first-line surgical option for stress urinary

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1 incontinence?

2 MR. SLATER: Objection.

3 THE WITNESS: Yes.

4 BY MR. SNELL:

5 Q. I believe plaintiffs' counsel -- strike
6 that.

7 I believe plaintiffs' counsel asked you
8 questions about the de-commercialization of certain
9 prolapse products earlier in your deposition.

10 Do you recall that?

11 A. Yep. Vaguely.

12 Q. Were those products decommissioned?
13 Strike that.

14 Were those products de-commercialized
15 because of safety concerns?

16 MR. SLATER: Objection.

17 THE WITNESS: No.

18 BY MR. SNELL:

19 Q. Who, if anyone, did an assessment as to
20 the risk-benefit and safety profile of those products
21 before the decisions were made?

22 A. Piet Hinoul, Aran Maree and myself, led by
23 Piet.

24 Q. And what was the determination, as led by
25 Dr. Hinoul?

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1 A. Similar to the others that we've discussed,
2 that the benefit-risk evaluations continued to
3 support safe and effective use.

4 Q. Now, have you looked at the Prolift label
5 from the time of launch and the updated label?

6 A. Yes.

7 Q. Do you believe that those labels
8 adequately disclosed the risks?

9 MR. SLATER: Objection.

10 THE WITNESS: Yes.

11 BY MR. SNELL:

12 Q. Now, would you --

13 MR. SLATER: Do you -- wait.

14 Do you seriously think this is getting
15 played to anybody?

16 MR. SNELL: I don't know. You asked him
17 about it so --

18 MR. SLATER: I --

19 BY MR. SNELL:

20 Q. Would you also rely -- would you rely on
21 Dr. Piet Hinoul's assessment of the adequacy of the
22 risks?

23 A. Yes.

24 MR. SLATER: Objection.

25 You've got to give me a second to object.

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1 MR. SNELL: That's fine.

2 BY MR. SNELL:

3 Q. For the Prolift.

4 MR. SLATER: Objection.

5 MR. SNELL: Let me just redo it, then you
6 object, because we're chopping.

7 BY MR. SNELL:

8 Q. Would you rely on Dr. Piet Hinoul's
9 assessment as to the risk-benefit analysis regarding
10 Prolift?

11 MR. SLATER: Objection.

12 THE WITNESS: Yes.

13 BY MR. SNELL:

14 Q. Would you rely on Dr. Piet Hinoul's
15 assessment as to whether the risks were adequately
16 conveyed on the Prolift?

17 MR. SLATER: Objection.

18 THE WITNESS: Yes.

19 BY MR. SNELL:

20 Q. And besides the instructions for use, can
21 risks also be conveyed in other manners?

22 MR. SLATER: Objection.

23 THE WITNESS: Yes.

24 BY MR. SNELL:

25 Q. One of the things you mentioned was

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1 professional education regarding the Ethicon
2 products.

3 Can risk information be conveyed in
4 professional education?

5 MR. SLATER: Objection.

6 THE WITNESS: Yes.

7 BY MR. SNELL:

8 Q. Are RFUs meant to reteach surgery?

9 MR. SLATER: Objection.

10 THE WITNESS: Please -- please say it
11 again?

12 MR. SNELL: Yeah.

13 MR. SHERIDAN: I didn't hear the first
14 part.

15 BY MR. SNELL:

16 Q. Are instructions for use meant to teach
17 the risks of surgery?

18 MR. SLATER: Objection.

19 THE WITNESS: No.

20 BY MR. SNELL:

21 Q. Are they meant to re-educate and train a
22 physician, who would learn about surgical risks
23 during his or her medical school, residency,
24 internship and fellowship, should he or she progress
25 that far?

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1 MR. SLATER: Objection.

2 THE WITNESS: No.

3 BY MR. SNELL:

4 Q. You were asked, I believe, about the
5 TVT-Secur quality boards, and the PowerPoint
6 plaintiffs' counsel marked was Exhibit T-1337.

7 Do you have it in front of you?

8 A. I do.

9 Q. And this -- in fairness, this is the
10 second quality board; correct?

11 A. It says quality board followup so I presume
12 that's accurate.

13 Q. Now, what is a quality board?

14 A. In our -- in our -- in the Ethicon quality
15 system it is the sort of final determining committee
16 to understand a product quality or safety or other
17 issue to help determine what, if any, action should
18 or should not be undertaken.

19 Q. And I'm not going to go back on to the
20 other exhibits plaintiffs' counsel marked, but one of
21 them, I believe, concerned complaints that Dr. Aran
22 Maree had received in Australia which got forwarded
23 up to Ethicon regarding TVT-Secur?

24 A. Yes.

25 Q. And you -- you were made aware of that at

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1 some point?

2 A. Yes.

3 Q. And the quality boards that were convened,
4 were they convened to investigate that matter?

5 A. I -- I can't recall whether that was the
6 only or specific matter, to be honest, but I believe
7 so.

8 Q. Well, this Exhibit 1337 on the followup
9 quality board, if you look at it, different complaint
10 reviews were done, as indicated in numerous pages
11 beginning with Page 3; is that correct or not?

12 MR. SLATER: Objection.

13 THE WITNESS: Yes.

14 BY MR. SNELL:

15 Q. Page 9 says, global complaint review,
16 Australia.

17 Let me know if you get there.

18 A. I'm there.

19 Q. The third bullet says, Australian
20 experience is not similar to U.S.A.

21 Did I read that correctly?

22 MR. SLATER: Objection.

23 THE WITNESS: You did.

24 BY MR. SNELL:

25 Q. Do you recall whether any changes or

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1 additions were made to the professional education
2 regarding TVT-Secur following this safety -- this
3 quality board?

4 A. I can't recall that specifically. What I
5 can recall is that it was felt that education was the
6 appropriate response so I -- I mean, I don't remember
7 that we said we're going to change the prof. ed.
8 decks or something.

9 Q. Is professional education one of the
10 options, an option, to address any issues that come
11 up in the use of product?

12 MR. SLATER: Objection.

13 THE WITNESS: Yes.

14 BY MR. SNELL:

15 Q. I want to go back to your experience that
16 plaintiffs' counsel asked you about.

17 In your experience, is the Prolene
18 polypropylene biocompatible?

19 MR. SLATER: Objection.

20 THE WITNESS: Yes.

21 BY MR. SNELL:

22 Q. Is the Prolene polypropylene safe and
23 effective?

24 MR. SLATER: Objection.

25 THE WITNESS: Yes.

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1 BY MR. SNELL:

2 Q. Plaintiffs' counsel asked you hypothetical
3 questions about if complaints came in on a product,
4 particularly TVT-Secur, about its decreased efficacy
5 in the hands of some surgeon, should that be --
6 information be made available to all surgeons.

7 MR. SLATER: Objection.

8 BY MR. SNELL:

9 Q. Do you recall, in general, those
10 hypothetical questions?

11 A. Yes.

12 MR. SLATER: Object to the
13 characterization of multiple other aspects of that
14 improper question.

15 MR. SNELL: Okay.

16 MR. SLATER: Just for the record, are you
17 suggesting that Ethicon wasn't being advised that
18 doctors in various countries couldn't get consistent
19 efficacy?

20 You don't have to answer the question.
21 You can continue. Go ahead.

22 MR. SNELL: We've already -- we've already
23 covered that.

24 MR. SLATER: Go ahead. I didn't want an
25 answer to that question.

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1 MR. SNELL: Yeah. I mean, if you want me
2 to answer it, I'll answer it, because I'll tell you I
3 know the data, and a lot of doctors get good results.

4 MR. SLATER: That's really good.
5 Continue.

6 MR. SNELL: Yeah.

7 MR. SLATER: Go ahead.

8 MR. SNELL: Don't ask me questions that
9 you don't want an answer to.

10 MR. SLATER: No. That's great. You know
11 what?

12 MR. SNELL: Come on, Adam. You're
13 smiling, I'm smiling. All right.

14 MR. SLATER: I love hearing a product
15 that's been pulled off the market getting defended.
16 Go ahead. Continue.

17 BY MR. SNELL:

18 Q. For example, you know, you're aware that a
19 few of the Australian surgeons had some complaints
20 about the efficacy of TVT-Secur.

21 MR. SLATER: Objection.

22 BY MR. SNELL:

23 Q. Correct?

24 A. Yes.

25 Q. Did that -- did those E-mails need to go

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1 to all the surgeons?

2 MR. SLATER: Objection.

3 THE WITNESS: No.

4 BY MR. SNELL:

5 Q. Is Ethicon's investigatory process
6 regarding those complaints a better way to handle
7 them?

8 MR. SLATER: Objection.

9 THE WITNESS: That's how they're handled,
10 yes.

11 BY MR. SNELL:

12 Q. And if changes are deemed to be needed or
13 additions are deemed to be needed in professional
14 education, is that an appropriate way of transmitting
15 information to other surgeons?

16 MR. SLATER: Objection.

17 THE WITNESS: Yes.

18 BY MR. SNELL:

19 Q. Doctor, do you recall that the -- towards
20 the end of the second day of your deposition you were
21 shown some certificates regarding different surgeons
22 who had underwent -- strike that.

23 Do you recall towards the end of your
24 second day of your deposition you were shown some
25 certificates by surgeons who had undergone some

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1 training on Ethicon Women's Health products?

2 A. Yes.

3 Q. Okay.

4 MR. SLATER: Objection.

5 MR. SNELL: Oh, here we go.

6 BY MR. SNELL:

7 Q. Exhibit 1330, 1331, 1332, a Dr. John
8 McNabb, do you recall, in general, being questioned
9 about these exhibits by plaintiffs' counsel?

10 A. Yes.

11 Q. These certificates say at the bottom, this
12 certificate in no way certifies the competency of
13 this physician, who may wish to perform the
14 procedures taught in this course; correct?

15 MR. SLATER: Objection.

16 THE WITNESS: Correct.

17 BY MR. SNELL:

18 Q. Does Ethicon certify physicians'
19 competency to perform pelvic floor surgery?

20 A. No.

21 Q. Does Ethicon credential surgeons to
22 perform pelvic floor surgery?

23 A. No.

24 Q. Is that why surgeons go to medical school,
25 residency, internships and fellowships?

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1 MR. SLATER: Objection.

2 THE WITNESS: Yes.

3 BY MR. SNELL:

4 Q. Plaintiffs' counsel asked you questions
5 about chronic pain.

6 My question to you is this: Is chronic
7 pain a risk of any surgery?

8 MR. SLATER: Objection.

9 THE WITNESS: Well, any surgery is a --
10 that's a big ticket, but certainly the preponderance
11 of surgery. I think you could probably find a minor
12 enough procedure that you wouldn't have chronic pain,
13 but for a -- for a substantive surgical procedure,
14 yeah, the risk of chronic pain exists.

15 BY MR. SNELL:

16 Q. Is chronic pain a risk of pelvic floor
17 surgery?

18 MR. SLATER: Objection.

19 THE WITNESS: Yes.

20 BY MR. SNELL:

21 Q. As to the current -- strike that.

22 In your current position do you have
23 products that fall under your umbrella of
24 responsibility that are those beyond the women's
25 health products?

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1 A. Yes.

2 Q. Approximately how many products do you
3 have under your responsibility? And you can -- if
4 it's more than a hundred or less than --

5 A. It's way more than a hundred. It's ten
6 companies.

7 Q. Okay. Who, if anyone, do you rely on to
8 assess the Ethicon Women's Health products from a
9 medical affairs standpoint?

10 A. The medical directors for that business
11 unit.

12 MR. SNELL: That's all I have.

13 Thank you.

14 MR. SLATER: Do you want me to proceed or
15 do you need a couple minutes?

16 MR. SNELL: Let's take a minute. I need
17 to go to the bathroom.

18 THE WITNESS: I wouldn't mind moving
19 around a little while I still can.

20 VIDEO OPERATOR: The time is now 7:36.

21 This is the end of Disk Number 5.

22 We're going off the record.

23 (Recess, 7:36-7:43 p.m.)

24 VIDEO OPERATOR: The time is now 7:43.

25 This is the beginning of Disk Number 6.

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1 We are back on the record.

2

3

EXAMINATION

4 BY MR. SLATER:

5 Q. Dr. Hart, I see you have the Prolift+M
6 clinical study protocol in front of you?

7 MR. SNELL: What exhibit is that, Adam?

8 MR. SLATER: It's -- 1340 is the final
9 protocol.

10 MR. SNELL: Oh, okay.

11 MR. SLATER: 1341.

12 THE WITNESS: '41.

13 MR. SLATER: Okay.

14 MR. SNELL: Is that one of them that I
15 covered?

16 MR. SLATER: No, you didn't.

17 BY MR. SLATER:

18 Q. Do you have that in front of you?

19 A. I do.

20 MR. SNELL: Just give me a second to get
21 to it, man, because I -- I separated them.

22 MR. SLATER: Well, I'm going to ask a
23 leading question while you find it.

24 BY MR. SLATER:

25 Q. Doctor, counsel asked you a little while

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1 ago if -- if you believed the Prolift was performing
2 as intended and you said yes.

3 Remember you said that?

4 MR. SNELL: Form. I'm not sure if that's
5 my question.

6 THE WITNESS: I don't remember the exact
7 words but I did -- I do remember that we talked about
8 the pelvic floor meshes, in general, performing as
9 expected and continuing to have safe and effective
10 profile. I think that's what I said.

11 BY MR. SLATER:

12 Q. If you could, turn in the profile -- in
13 the protocol for the Prolift+M to the -- to Page 31.

14 A. Uh-huh.

15 Q. And just so I understand, and confirm this
16 to me, the Prolift performing as intended in a safe
17 and effective way means for you that the adverse
18 events with the Prolift would include mesh exposure,
19 which -- which is described as a common complication.

20 That's the first one listed there; right?

21 A. It is.

22 MR. SNELL: Form.

23 BY MR. SLATER:

24 Q. Would also include mesh retraction, which
25 can cause vaginal anatomic distortion, which may

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1 eventually have a negative impact on sexual function
2 and this can also lead to pain and, in fact, chronic
3 pain; right?

4 That's another adverse event that can
5 occur from the Prolift; right?

6 A. Yes.

7 Q. Also, the scar plate that forms with
8 ingrowth of tissue into the mesh can cause stiffness
9 in the vagina that further impacts sexual function in
10 a negative manner.

11 That's another part of the Prolift
12 performing as intended in a safe and effective way?
13 Is that your testimony to this jury?

14 A. No. No. These are anticipated adverse
15 device effects that could occur at a certain rate.
16 And when you do the -- when you do the benefit-risk
17 analysis, you would balance the observed rates versus
18 the -- the benefit achieved and make your
19 benefit-risk judgment based on that.

20 Q. In deciding that the Prolift is safe, your
21 company believed that the occurrence of these types
22 of complications and the other ones that I've asked
23 yourself about and other medical affairs people, that
24 all still, even though all that was known to your
25 company, you say, oh, Prolift was still safe; is that

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1 right?

2 A. That's correct. Based on the observations
3 and the clinical data that was -- or the clinical
4 research that was done and looking at the observed
5 rates.

6 Q. Well, in fact, your company never studied
7 and tried to determine what the rates were of the
8 most serious complications with the Prolift. It's
9 something your company never studied.

10 A. It was --

11 MR. SNELL: Form, foundation on that.

12 THE WITNESS: They were -- they were
13 collected as adverse events in the clinical research
14 that had -- that was done.

15 BY MR. SLATER:

16 Q. What I'm saying is this: There is no
17 study your company ever performed to try to assess
18 and determine the rates of the most serious
19 complications that were occurring with the Prolift.
20 It's not something you studied.

21 MR. SNELL: Form and foundation.

22 THE WITNESS: It's part of every clinical
23 research study that's done.

24 BY MR. SLATER:

25 Q. Can you point to me one paper or study

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1 that was devoted to studying the rates of the most
2 serious complications with the Prolift?

3 A. As a primary end point?

4 Q. Yes.

5 A. No.

6 Q. Prolene Soft mesh is the name of the mesh
7 material that is in the Prolift; correct?

8 A. Yes.

9 Q. We spoke earlier about information and
10 whether it should be placed in the IFU and counsel
11 asked you some questions about that as well in
12 followup to my questioning; right?

13 A. Right.

14 Q. Tell me if I understand correctly.
15 Ultimately, it's from your viewpoint and knowing how
16 things work in your company, medical affairs has
17 information about the benefits and risks but
18 regulatory ultimately makes the final determination
19 as to what would be placed into the IFU because
20 that's a regulatory document.

21 Do I understand that correctly?

22 A. It's a -- yeah, it's a regulatory document
23 that medical affairs has absent -- you know, has
24 input to, yes.

25 Q. Medical affairs has input but regulatory

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1 makes the decision about what actually has to be
2 placed into the document and how it should be worded.

3 Am I -- do I understand that correctly?

4 A. So -- so the IFU is developed as a team
5 effort with a -- with a number of cross-functional
6 team or members and all of those have input and --
7 and the ability to -- to change. So are you asking
8 me, would a regulatory person overrule something
9 about -- from a medical standpoint? Is that what
10 you're asking?

11 Q. What I'm asking is --

12 A. They -- they -- they own the document and
13 they submit it to the agency.

14 Q. The -- the regulatory affairs
15 professionals in your company are the ones who are
16 looked to for the ultimate expertise on what types of
17 information has to be in an IFU, for example, and how
18 it should be phrased to comply with the regulations
19 that govern that type of a document.

20 A. I don't know about --

21 MR. SNELL: Form.

22 THE WITNESS: I don't know about the
23 phrasing, no.

24 BY MR. SLATER:

25 Q. Regulatory affairs would know what's

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1 required by the FDA regulations and what type of
2 information would need to be included. They would
3 look to medical affairs to give them the information
4 so they could then determine what gets put in the
5 IFU?

6 A. Yeah. Yeah. I mean, that's a -- that's a
7 simplification, I would say.

8 Q. But an accurate simplification?

9 A. So regulatory -- yes, regulatory affairs
10 would own the document, would have -- be advising the
11 entire cross-functional team about what sort of
12 information is needed, the team would provide that
13 information, and then as a group they would author
14 the IFU.

15 Q. Have you or anyone, to your knowledge,
16 actually studied the question of whether or not the
17 cytotoxicity of any of your pelvic mesh devices
18 causes erosions or exposures in actual clinical use?

19 MR. SNELL: Foundation.

20 THE WITNESS: No.

21 BY MR. SLATER:

22 Q. With regard to whether or not any of your
23 company's pelvic mesh devices can cause cancer, you
24 would agree with me that it is possible that over the
25 long term, perhaps 20 or 30 years, it can turn out,

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1 yes, in fact, they do cause cancer or increase the
2 risk of cancer.

3 You have no way to exclude that; right?

4 MR. SNELL: Form.

5 THE WITNESS: I can't exclude it.

6 BY MR. SLATER:

7 Q. Is Johnson & Johnson in the business of
8 withdrawing safe and effective medical devices from
9 the market?

10 A. Yes.

11 Q. Can you tell me why that is done?

12 A. Yeah. As -- so as J&J looks at its -- so I
13 can only speak on the device side, I haven't worked
14 on the pharma side, but J&J looks at its portfolio of
15 products because the MD&D businesses, they will --
16 so -- so it's a zero-sum gain. They will prioritize
17 programs and make determinations sometimes to -- to
18 divest a company or withdraw products from the
19 marketplace even though they're safe and effective
20 just so -- just as a matter of a business decision.

21 Q. If you could, look at the document 1317.
22 It's the PowerPoint from the meeting with the FDA.

23 A. Which stack? This stack? Okay.

24 Q. If you could, go to Page 48.

25 A. Okay.

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1 MR. SNELL: Which one now? 1317, you
2 said?

3 BY MR. SLATER:

4 Q. Again, this is the PowerPoint that was
5 actually utilized in the presentation to the FDA;
6 correct?

7 A. I believe so, yes.

8 Q. And on Page 48 there's a slide that was
9 presented to the FDA that says, surgeon- and
10 science-based development, and gives them an overview
11 of all the different things your company does to
12 determine safety of your devices; right?

13 A. I need -- I need to study this. I'm not
14 familiar with this slide at this point.

15 Yeah. So what was your question then?

16 MR. SLATER: Read it back, please.
17 Actually, I'll re-ask it. I'll ask it differently.

18 BY MR. SLATER:

19 Q. Here on Page 48 the FDA was presented with
20 things that your company does in developing pelvic
21 mesh devices; right?

22 A. Yeah. It looks like a high-level kind of
23 summary.

24 Q. One of the things that is listed is
25 preclinical testing for biocompatibility; right?

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1 A. Right.

2 Q. Did you or anybody on the team of people
3 that met with the FDA tell the FDA that cytotoxicity
4 testing of any of your pelvic mesh had shown marked
5 or severe cytotoxicity? Was that disclosed to the
6 FDA?

7 A. At this meeting? No.

8 Q. Was that ever disclosed? Well, rephrase.
9 Withdrawn.

10 MR. SNELL: I'll -- I'll --

11 MR. SLATER: Burt.

12 MR. SNELL: What?

13 MR. SLATER: Oh, my gosh.

14 Okay. Let's go to the other PowerPoint,
15 the mesh platform review, November 2010.

16 BY MR. SLATER:

17 Q. This is the review that took place after
18 the Iglesia study was published?

19 A. Yeah. Got it.

20 Q. Were you aware that there was an exchange
21 of E-mails between your medical affairs department
22 and Dr. Sokol, one of the authors?

23 A. I don't think so.

24 MR. SHERIDAN: What's the exhibit number?
25 Do you know what the exhibit number is?

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1 MR. SNELL: I don't know which one you're
2 talking about.

3 MR. SLATER: Hart D-1.

4 MR. SNELL: Oh, okay.

5 BY MR. SLATER:

6 Q. If you'd turn about halfway along --

7 MR. SNELL: Give me a second. Thank you.

8 BY MR. SLATER:

9 Q. -- you were asked about a page that says,
10 pain, IUGA, '01 to '08?

11 A. I have it.

12 Q. And what this slide is showing is reports
13 of various complications --

14 A. Oh, wait.

15 Q. -- that would cause pain in a patient;
16 correct?

17 A. I'm sorry. I don't have the right page. I
18 have erosion rates. Is it before that?

19 Q. It was after. It's after the erosion
20 rates. This is a page counsel actually asked you
21 about.

22 A. Okay.

23 Q. Counsel asked you about this slide, pain,
24 IUGA, '01 to '08.

25 A. Uh-huh.

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1 Q. Right?

2 And this chart talks about what the study
3 showed with regard to complications on the left that
4 lead to pain.

5 That's what this is laying out; right?

6 A. Yeah.

7 Q. And the last column is, mesh retraction,
8 and it's pointing out that for the Prolift there's a
9 12.3 percent painful mesh retraction rate, per
10 whatever studies are, 30 studies are being looked at
11 there; right?

12 MR. SNELL: Form --

13 THE WITNESS: Yeah.

14 MR. SNELL: -- and foundation.

15 Go ahead.

16 THE WITNESS: Yeah. I don't know that
17 this is related to -- I understand it says pain on
18 the top, and I don't know that this is painful mesh
19 retraction rates, but it says mesh retraction rates.

20 BY MR. SLATER:

21 Q. This is a page devoted to pain.

22 A. Right.

23 Q. It would make sense that this is mesh
24 retraction that is considered to be painful,
25 otherwise, why list it on a page that's devoted to

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1 pain?

2 A. Because it's recognized that that's at
3 least a contributing factor and could be. So I don't
4 know that all 12.3 percent of these people had
5 painful contraction.

6 Q. Well, on this page that is titled pain, 30
7 Prolift studies were looked at and came up with a
8 12.3 percent mesh retraction rate; right?

9 A. Right.

10 Q. And for the TVM study it says 13.2 percent
11 mesh retraction.

12 You see that?

13 A. Yes.

14 Q. And it says 11 out of 90 and then 6 out of
15 39.

16 Do you see that?

17 A. I do.

18 Q. Are you aware that in the TVM study that
19 the U.S. arm of the study did not actually look for
20 mesh retraction? It wasn't an end point to be
21 documented in the patient case report forms?

22 MR. SNELL: Form.

23 THE WITNESS: I -- I can't say that I'm
24 aware, yes or no.

25 BY MR. SLATER:

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1 Q. Go to the -- were you -- rephrase.

2 Were you aware that in a study performed
3 by Professor Jacquetin, Dr. Fatton that they made a
4 presentation to IUGA and had shown a 19.6 percent
5 painful mesh contraction rate with the Prolift?

6 MR. SNELL: Foundation.

7 THE WITNESS: Not as I sit here, no.

8 BY MR. SLATER:

9 Q. No one in medical affairs told you they
10 were aware of that, did they?

11 A. I don't know. I mean, I don't recall it
12 right now.

13 Q. You were asked about suture erosions in
14 the Iglesia study. Remember that?

15 A. Yes.

16 Q. Those -- those -- rephrase.

17 Those suture erosions, like any suture
18 erosion, were easily treated. The suture was removed
19 and the patient healed and that was the end of that;
20 right?

21 A. I don't know that. They did say they
22 removed some of them.

23 Q. We had --

24 A. I don't know about the -- I don't know the
25 outcome but they --

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1 Q. I was reading through the -- and I'm
2 trying to save time but you can look at it. I read
3 through the paper as the questioning was going on.

4 MR. SNELL: You should look at it.

5 Let him look at it.

6 MR. SLATER: You know, I'm going to ask
7 the question --

8 MR. SNELL: Okay.

9 MR. SLATER: -- and then Dr. Hart will do
10 what he's going to do but --

11 MR. SNELL: Okay.

12 MR. SLATER: -- you know, I know you want
13 to be here all night. Everyone else wants to
14 actually go home.

15 BY MR. SLATER:

16 Q. Let me ask you this.

17 MR. SNELL: I object to that.

18 BY MR. SLATER:

19 Q. You understand that a suture erosion is
20 different in magnitude, in treatability, and in many
21 significant ways from Prolift mesh erosion.

22 A. Exposure?

23 Q. Yes.

24 MR. SNELL: Form.

25 BY MR. SLATER:

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1 Q. As a general proposition, you're talking
2 about, basically, two different things.

3 A. They're two different things.

4 Q. And in terms of treatability, there may be
5 some mesh exposures with the Prolift that can be
6 treated expeditiously but we know that there are some
7 patients for whom they end up with complex mesh
8 erosions that are treated repeatedly and the patient
9 never actually is successfully treated; right?

10 MR. SNELL: Foundation, form.

11 THE WITNESS: Yes. But I'm also aware
12 that there can be difficult suture exposures as well.

13 MR. SLATER: Move to strike from "but"
14 forward.

15 BY MR. SLATER:

16 Q. Are you familiar with any literature that
17 points out patients with a suture erosion that led to
18 permanent, life-altering pain for a patient?

19 A. So my -- my experience would be personal
20 and in -- and in surgery where we had a number of
21 people that would -- that would develop suture
22 erosions over their sternum and could end up with a
23 chronic osteomyelitis that was painful for a long
24 time. Not common, but I certainly had the
25 experience.

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1 Q. Are you aware of any literature that talks
2 about a suture erosion in a vagina or pelvis leading
3 to chronic, permanent, life-altering pain?

4 A. Not as we sit here, no.

5 Q. If you'd turn forward several pages,
6 there's a page that says, submitted IIS Altman, et
7 al, paper.

8 A. Trying to see roughly how deep you are in
9 the deck.

10 Q. Maybe ten pages.

11 A. Ten in?

12 Q. Yeah, maybe ten pages.

13 A. Ten in.

14 MR. SHERIDAN: In from the back.

15 BY MR. SLATER:

16 Q. Ten further. Ten further to the back.

17 A. Yes.

18 Q. It says, submitted IIS Altman paper. And
19 as part of this presentation, you and others who this
20 was presented to were told about this study that
21 Altman had done and that was submitted to The New
22 England Journal of Medicine, and that was going to be
23 an important part of trying to answer the Iglesia
24 study; right?

25 A. I don't know if it's an important part of

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1 answering it but would be another bolus of
2 information to be evaluated.

3 Q. At the very bottom they're -- well,
4 rephrase.

5 This page is talking about findings in the
6 Altman study. And you see the last point, it says,
7 the rate of dyspareunia was 34 percent in the
8 colporrhaphy group compared to 51 percent in the mesh
9 group.

10 A. A different page?

11 Q. There are several pages that say,
12 submitted IIS Altman paper.

13 A. Uh-huh.

14 Q. What I just read is right here at the
15 bottom of the page, the rate of dyspareunia.

16 A. Yes.

17 Q. Now, you can hold that page, and then do
18 you have -- do you have the Altman actual article?

19 MR. SNELL: Is that my copy, Adam, or
20 yours?

21 MR. SLATER: It's your copy.

22 MR. SNELL: So I'm going to need it back.

23 MR. SLATER: That's fine.

24 THE WITNESS: Not in today's group, huh?

25 MR. SLATER: It is. You were asked about

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1 it by counsel.

2 THE WITNESS: Yeah. But --

3 MR. SNELL: I don't think I showed it to
4 him. I just asked him.

5 MR. SLATER: You did. He was going
6 through the charts and everything.

7 MR. SNELL: You're right. You're right.
8 I did. I take it back.

9 MR. SLATER: You shouldn't have. You
10 shouldn't have but you did.

11 MR. SNELL: Come on now. You shouldn't go
12 there because you know where I'm going to go.

13 MR. SLATER: Burt, I've got to tell you, I
14 don't really care where you go.

15 THE WITNESS: Oh.

16 That's not it.

17 MR. SLATER: Can you give him a hand
18 looking for it, Burt? You're sitting there.

19 MR. SNELL: I don't have it. I don't have
20 an extra copy. That's why I had to give him that
21 one.

22 MR. SLATER: You gave a copy of Doctor --

23 MR. SNELL: No. No. That's why I had to
24 give him my copy. Remember?

25 MR. SLATER: Oh. There's no other copy in

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1 existence in this room?

2 MR. SNELL: No.

3 MR. SLATER: All right. Then this is what
4 I'm going to do: If this is the only copy, you're
5 wasting your time. I didn't even know that.

6 MR. SNELL: Yeah, that's another problem.

7 MR. SLATER: Let me just make a note here.

8 MR. SNELL: They didn't print out copies
9 of the older exhibits that were marked during Days 1
10 and 2, only the new ones.

11 THE WITNESS: I didn't know you could have
12 a third wind.

13 MR. SLATER: Oh, I'm good.

14 THE WITNESS: No. I'm talking about me.
15 I didn't know I could have a third wind.

16 MR. SLATER: Oh, you're doing good too.

17 This is the copy, this is the counsel's
18 copy.

19 MR. SNELL: Okay.

20 THE WITNESS: Okay.

21 MR. SLATER: Let me start over.

22 BY MR. SLATER:

23 Q. Now, Doctor, I've handed you the actual
24 article that was published in The New England Journal
25 of Medicine for the Altman study.

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1 See that?

2 A. I do.

3 Q. And this is what I want to ask you: Can
4 you show me where in that article it discloses that
5 the rate of dyspareunia was 34 percent in the
6 colporrhaphy group and it was 51 percent in the mesh
7 group?

8 Can you show me where those percentages
9 are actually stated in that article? I -- and I'm
10 going to tell you, I read through it multiple times
11 and I can't find those numbers but --

12 A. Well, for me to say no I guess I have to
13 read it.

14 Q. Take a look. Dyspareunia is -- is
15 discussed in a few different places. It's discussed
16 at the top of Page 1834. They just say it's a higher
17 rate but they don't give the percentages.

18 I don't see anywhere where those numbers
19 are actually reflected in the article. If they are,
20 please show it to me.

21 A. Whoops. I thought I had marked it. No.

22 Q. So just to be clear, in November of 2010 a
23 presentation was made by medical affairs regarding
24 the Iglesia study and in that context the Altman
25 study, which had been submitted to The New England

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1 Journal of Medicine, was discussed and on this one
2 page here we see that your company was aware of the
3 rate of dyspareunia was 34 percent in the
4 colporrhaphy group compared to 51 percent in the mesh
5 group; correct?

6 A. It says that here, yes.

7 Q. And I've just given you as much time as
8 you needed to go through the actual published article
9 in The New England Journal of Medicine and those
10 statistics of 34 percent versus 51 percent are not
11 found in the article; right?

12 A. I do not see that.

13 Q. Are you aware that when David Robinson was
14 provided a draft -- well, rephrase.

15 Are you aware that when your company's
16 medical affairs people, including David Robinson,
17 looked at the manuscript draft, that David Robinson
18 showed alarm at those numbers and communicated to Dr.
19 Altman that that was a serious concern of his?

20 A. No, I'm not aware.

21 Q. If, in fact, David Robinson's showing of
22 concern at those numbers, which he referred to as --
23 I'm paraphrasing -- very high numbers, led Dr. Altman
24 to remove those numbers from the study, that would be
25 a real serious issue, wouldn't it?

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1 MR. SNELL: Foundation. Form.

2 MR. SLATER: I'm sorry. One second.

3 What's your objection?

4 MR. SNELL: Yeah. If -- if -- if --

5 foundation. You haven't laid a foundation that that

6 had any bearing whatsoever on Dr. Altman or any of

7 his other 52 investigators' decision about what to do

8 on that manuscript. That's the foundation.

9 MR. SLATER: Okay.

10 MR. SNELL: Form is vague.

11 Go ahead.

12 MR. SLATER: Okay.

13 BY MR. SLATER:

14 Q. You can answer the question.

15 A. Say -- I'm sorry. One more time.

16 Q. I'll ask it again.

17 A. Uh-huh.

18 Q. David Robinson, as a medical affairs

19 director in Ethicon, should not have been attempting

20 to influence Dr. Altman to remove those statistics

21 from the manuscript.

22 That's something he -- he should not be

23 doing; correct?

24 MR. SNELL: Foundation.

25 THE WITNESS: Not -- not knowing the

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1 protocol and -- and -- and the definitions and all
2 that sort of thing, I would want to know more about
3 what does this -- what does this mean, how was it
4 defined, and when was it measured and all that sort
5 of stuff, but I don't think -- I would not expect
6 medical affairs to try to influence the scientific
7 dis -- evidence or dissemination of -- of important
8 scientific information.

9 BY MR. SLATER:

10 Q. And, again, as you sit here now, you're --
11 have you ever -- well, let me ask you this: Have you
12 ever looked at the documents, your internal
13 documents, with the commentary -- the comments and
14 the editing by Piet Hinoul, David Robinson, Aaron
15 Kirkemo and Judi Gauld into the Altman draft
16 manuscript which was then sent back to Dr. Altman?

17 A. I don't think so.

18 Q. So as I'm -- as you sit here now, you're
19 hearing this for the first time from me that David
20 Robinson showed serious concern about those numbers
21 and expressed that to Dr. Altman.

22 A. I can't remember --

23 MR. SNELL: Form.

24 THE WITNESS: I can't remember if we
25 talked about it two weeks or two months ago or not

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1 but...

2 BY MR. SLATER:

3 Q. We went through the IIS protocol that went
4 into effect as of 2009.

5 If the interaction between David Robinson
6 and the other medical affairs and clinical affairs
7 person happened with Dr. Altman after that time, then
8 they certainly were duty bound not to make any effort
9 or say anything that might influence the reporting of
10 the data, for example, that could have influenced Dr.
11 Altman to remove those numbers.

12 That's not what they're supposed to be
13 doing; right?

14 MR. SNELL: Form. Foundation.

15 THE WITNESS: So I -- again, my -- my --
16 it's the same question, same answer.

17 If -- it would not be expected that the
18 medical affairs team would interfere with
19 important -- or dissemination of important scientific
20 information.

21 BY MR. SLATER:

22 Q. You would agree there's a big difference
23 between saying that the rate of dyspareunia with the
24 Prolift was higher than the rate of dyspareunia with
25 the colporrhaphy, on the one hand, versus actually

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1 giving these numbers to people who would read the
2 article and telling them that the difference is 34
3 percent to 51 percent.

4 There's a -- there's a qualitative
5 difference; correct?

6 A. Yeah, it's more informative with the
7 numbers.

8 MR. SLATER: Off the record for a second.

9 VIDEO OPERATOR: Time is now 8:17.

10 We're going off record.

11 (Discussion off the record.)

12 VIDEO OPERATOR: Time is now 8:18.

13 We are back on the record.

14 BY MR. SLATER:

15 Q. Doctor, you said that you were not aware
16 of any evidence of a relationship between
17 polypropylene mesh and cancer.

18 Remember you said that?

19 A. That --

20 MR. SNELL: That misstates form.

21 Go ahead.

22 THE WITNESS: Yes.

23 BY MR. SLATER:

24 Q. You remember seeing the Material Safety
25 Data Sheet for the -- the Prolene material that goes

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1 into the polypropylene?

2 A. Yes.

3 Q. Let me ask it differently. I mixed the
4 two terms.

5 Do you remember we showed you the Material
6 Safety Data Sheet for the -- the raw polypropylene
7 material that goes into the Prolene?

8 A. Yes.

9 Q. And it showed that testing had shown that
10 exposure to the material had caused sarcomas in rats?

11 MR. SNELL: Foundation.

12 THE WITNESS: Rodents or rats, yes.

13 BY MR. SLATER:

14 Q. That's cancer; right?

15 A. Yes. It's sarcoma. It's not carcinoma,
16 it's sarcoma.

17 Q. Sarcoma. But that's -- that's cancerous;
18 correct?

19 MR. SNELL: Form, foundation.

20 THE WITNESS: It's malignancy.

21 BY MR. SLATER:

22 Q. It's an indication that the material can
23 cause cancer; correct?

24 MR. SNELL: Same objection.

25 THE WITNESS: Sarcoma in a rat in -- in --

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1 in a -- in that mechanical or -- yeah, mechanical
2 form or, you know what I mean, in disk form.

3 BY MR. SLATER:

4 Q. The answer is yes, that's an indication
5 that the material can be cancerous?

6 A. In rats.

7 MR. SNELL: Form.

8 BY MR. SLATER:

9 Q. Well, the reason they test it in rats is
10 because they think that that gives an indication of
11 what would happen in a human being.

12 That's why they do the testing in the
13 rats; right?

14 MR. SNELL: Foundation.

15 THE WITNESS: That's one of the tests that
16 can be done, yes.

17 BY MR. SLATER:

18 Q. You were asked by counsel about statements
19 by AUGS and AUA regarding their viewpoint on the TVT.
20 Remember that?

21 A. I do.

22 Q. Do you know which doctors within the
23 professional organizations wrote those position
24 statements?

25 A. No.

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1 Q. Do you know whether those doctors had
2 financial relationships with medical device or
3 pharmaceutical companies?

4 A. No.

5 Q. Do you know if medical device or
6 pharmaceutical companies had input behind the scenes
7 into those position statements?

8 A. No, not directly.

9 Q. Did your company share all of its internal
10 documents regarding TVT with those professional
11 organizations so they would not only know what was
12 publicly available but also know all of the internal
13 knowledge that your company had before they issued
14 those position statements?

15 A. Not that I'm aware of.

16 Q. Did your company tell those professional
17 organizations that testing of the Prolene mesh had
18 shown that it was cytotoxic?

19 MR. SNELL: Form.

20 THE WITNESS: No, not that I know of.

21 BY MR. SLATER:

22 Q. One of the bases for your company to
23 conclude that TVT Prolene mesh would be safe and
24 effective was the history of the use of Prolene
25 hernia mesh; correct?

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1 A. Yeah, that experience was an input.

2 Q. Now, let me ask you a question about a
3 process: When your company seeks clearance for a
4 product or a device from the FDA under the 510(k) and
5 says, well, this is -- these are the predicate
6 devices -- you understand what a predicate device is;
7 right?

8 A. High level, yes.

9 Q. Okay. Basically, you say, we want to get
10 clearance for this device because it's substantially
11 equivalent to this other device, and that would be
12 the predicate.

13 You understand that; right?

14 A. Yes.

15 Q. And if your company is going to rely on a
16 predicate device, your company should have an
17 understanding of whatever information is available
18 regarding the safety and effectiveness of the
19 predicate.

20 Stands to reason; right?

21 A. Right.

22 Q. And are you aware that for Prolene hernia
23 mesh the predicate or one of the predicates was Bard
24 Marlex hernia mesh?

25 A. Not aware, no.

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1 Q. I'm going to -- I'm going to tell that you
2 as a statement of fact. It's been established
3 through deposition testimony.

4 MR. SNELL: You mean a regulatory
5 predicate?

6 BY MR. SLATER:

7 Q. I'm going to tell you as a statement
8 because I don't have the documents here, but in the
9 deposition of Peter Ciccini this was established for
10 the record that one of the predicates for Prolene
11 hernia mesh was Bard Marlex hernia mesh. Okay?

12 A. Okay.

13 Q. So your company would have needed to be
14 aware of whatever information was available regarding
15 safety and effectiveness of the Bard Marlex hernia
16 mesh; right?

17 MR. SNELL: Form, foundation.

18 BY MR. SLATER:

19 Q. Correct?

20 A. Yeah.

21 Q. And your company, for example, would have
22 needed to be aware of if there was information
23 indicating that this predicate device, that a warning
24 had been provided by the manufacturer of the raw
25 material that it should not be used in the human body

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1 as a medical device.

2 That's something your company would need
3 to know in that context; right?

4 MR. SNELL: Foundation, form.

5 THE WITNESS: Certainly would want to know
6 it and then evaluate what it meant.

7 BY MR. SLATER:

8 Q. And as you sit here now, you don't know if
9 medical affairs in your company knew that or not.

10 A. I don't know that. Preceded me by a long
11 shot.

12 Q. And, in fact, now, if we take the chain
13 back, your company is basic -- has basically said,
14 look -- well, rephrase.

15 If we take the chain back, your company
16 said, okay, one of the bases to say TVT Prolene mesh
17 will be safe is we have this Prolene hernia mesh over
18 there.

19 If you take the chain back, that was
20 marketed based, in part, on reliance on Bard Marlex
21 hernia mesh. And if you take the chain back, that
22 MSDS for the raw Marlex material would be something
23 that your company would need to take into account
24 when saying that those Prolene meshes are safe and
25 effective; correct?

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1 MR. SNELL: Foundation and form.

2 BY MR. SLATER:

3 Q. You can answer.

4 A. I would think -- I would think it would be
5 one of the inputs, and you would evaluate it in
6 context, yes.

7 Q. And, to your knowledge, that did not
8 occur, as far as you know.

9 A. I don't know, yes or no.

10 Q. Let's go to -- see what you have close by.
11 You were asked a question by counsel,
12 well, your company cited certain statements --
13 rephrase.

14 In these marketing documents we went
15 through your company made certain statements and
16 referenced certain medical literature for the -- as
17 support to make those statements; right?

18 A. Right.

19 Q. And I think counsel asked you and you
20 said, well, you know, doctors can read the articles;
21 right?

22 Remember that?

23 A. They certainly can, yes.

24 Q. You certainly want doctors to read a
25 marketing document from your company that summarizes

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1 medical literature and believe that your company is
2 accurately and in a fair and balanced way summarizing
3 that medical literature; right?

4 A. Right.

5 Q. And you want doctors to feel that they
6 have so much confidence in your company that they can
7 trust that when something is stated in a marketing
8 document and there's a reference, they don't need to
9 read the article, they can trust that your company is
10 telling them the truth about what that article says;
11 right?

12 A. Well, I believe that the marketing
13 materials are typically pretty -- pretty brief and,
14 you know, succinct and the -- the references are
15 there for -- for clarity or for more information for
16 the physician.

17 MR. SLATER: Move to strike.

18 THE WITNESS: Just another way for them
19 to -- to understand what the pieces means.

20 MR. SLATER: Move to strike.

21 Can you just read the question back?

22 I'd just ask you to try to answer the
23 direct question, if we could. And I'm actually going
24 to try to wrap it up, despite our little spat, and
25 maybe counsel will reconsider and not keep going

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1 around this bush.

2 MR. SNELL: Did you move to strike that?

3 MR. SLATER: Yeah, I did.

4 MR. SNELL: Mark that, because I want that
5 in the record.

6 Go ahead.

7 MR. SLATER: Determination. One of the
8 five D's.

9 MR. SNELL: Don't give up.

10 MR. SLATER: Read the question back.

11 (The court reporter read the requested
12 portion of the record.)

13 THE WITNESS: Oh, I thought -- I thought
14 you were striking something forward or something.

15 MR. SLATER: No. I'm asking you, can you
16 answer that question?

17 THE WITNESS: I did.

18 MR. SNELL: Yeah, he did.

19 MR. SLATER: Well, I'm asking for a yes or
20 no answer.

21 MR. SNELL: Form, asked and answered twice
22 now.

23 THE WITNESS: I'm really sorry.

24 MR. SLATER: We're about to -- she's going
25 to read the -- the court reporter will read the

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1 question back to you again.

2 I'm asking you, can you answer the
3 question with a yes or no answer?

4 THE WITNESS: Well, I'll see if I can or I
5 can't.

6 MR. SLATER: Fair enough.

7 MR. SNELL: And I'm going to object to
8 form as asked and answered.

9 MR. SLATER: You have your objection. You
10 don't have to keep saying it.

11 Please read it back.

12 (The court reporter read the requested
13 portion of the record.)

14 THE WITNESS: No. And I'm -- and I'll
15 explain. I -- I believe that a marketing piece
16 will -- well, a bug.

17 BY MR. SLATER:

18 Q. Go ahead.

19 A. With a -- with references is -- is there
20 for a reason, to provide the opportunity for the
21 surgeon to get more clarity on a very brief
22 statement.

23 MR. SLATER: Move to strike after "no."

24 BY MR. SLATER:

25 Q. Your company in a marketing document makes

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1 claims, makes statements --

2 A. Uh-huh.

3 Q. -- and provides references, and what
4 you're saying to a doctor is, we have support for
5 what we're saying. Here's the support and this is
6 what that -- in this case, this is what that medical
7 article says. Right?

8 A. Yes.

9 Q. And you want doctors to believe you when
10 you make that representation; right?

11 A. Yes.

12 Q. You wouldn't criticize a doctor for
13 believing what you say in your marketing documents,
14 would you?

15 A. If they didn't have any -- if they -- if
16 they didn't have questions.

17 Q. I mean, you wouldn't say, for example, if
18 a doctor were to testify at trial, well, I believed
19 this representation and that was the reason I used
20 this device, and if I had known that the answer was
21 different or if I had known this other information, I
22 wouldn't have used it, you wouldn't say back to that
23 doctor, well, you were -- you believed what we said
24 in this marketing document, you didn't go back and
25 read the reference to see that we didn't really

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1 represent accurately what it was, well, shame on you.

2 That wouldn't be your response, would it?

3 MR. SNELL: Foundation and form.

4 Go ahead.

5 THE WITNESS: No.

6 BY MR. SLATER:

7 Q. You were asked about the IFU. I want to
8 ask you a question about this in terms of you were
9 asked about what type of information would be in
10 there.

11 The standard is not that you need
12 level-one evidence that an adverse reaction exists
13 before you'll put it in the IFU. That's not the
14 standard; right?

15 A. No, not all the time.

16 Q. Oftentimes, information is put into an IFU
17 based on anecdotal feedback to the company.

18 That happens; right?

19 A. Anecdotal feedback.

20 Q. Yeah. Where, for example, surgeons in
21 meetings with medical affairs or with marketing
22 people are providing information about an adverse
23 event that they're seeing, your company will at times
24 use that as the basis to give a warning in an IFU.

25 A. I'm not aware of that. I think

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1 observational study or more -- more substantial
2 information than just a -- just a casual anecdote
3 from a surgeon.

4 Q. Well, your company does not need a
5 published article --

6 A. No.

7 Q. -- finding that an adverse event occurs
8 before you'll put it into an IFU.

9 That's not the standard; right?

10 A. That's correct.

11 Q. The marketing document that looks like
12 this, Exhibit 1348, counsel asked you about, I have a
13 question about that. It's not part of that document.

14 A. Right.

15 Q. You got it. You're -- you're two away.

16 A. Let me see the front it. Is that it?

17 Q. Next one.

18 A. Next one.

19 Q. 1348.

20 A. Yeah.

21 Q. Exhibit 1348, look at the fourth page, the
22 one that says -- that counsel asked you about -- only
23 Gynecare TVT uses Prolene polypropylene mesh.

24 You see that?

25 A. I do.

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1 Q. Just above the picture it says, tissue
2 incorporation. Large pores result in good
3 incorporation.

4 Do you see that?

5 A. I do.

6 Q. In fact, Prolene mesh is a microporous, a
7 small-pore mesh, not a large-pore mesh; correct?

8 MR. SNELL: Foundation.

9 MR. SLATER: I'm sorry. Are you okay?
10 You have a very pained look on your face.

11 MR. SNELL: Yeah. That's --

12 MR. SLATER: You actually think Prolene
13 mesh is macroporous?

14 MR. SNELL: Of course, it is.

15 MR. SLATER: Okay.

16 MR. SNELL: Of course, it is.

17 MR. SLATER: You should honestly --

18 MR. SNELL: Foundation on that all day
19 long.

20 Go ahead.

21 BY MR. SLATER:

22 Q. Doctor, you -- rephrase.

23 This document says that large pores result
24 in good incorporation.

25 Are you aware of the fact that Prolene

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1 mesh, the mesh used in the TVT, is considered a
2 heavyweight, small-pore mesh?

3 MR. SNELL: Foundation.

4 THE WITNESS: No.

5 BY MR. SLATER:

6 Q. You don't know that?

7 A. No.

8 Q. Do you believe it to be a lightweight
9 mesh?

10 A. No. It's -- it's the Prolene. No, it's
11 not the same as Ultrapro.

12 Q. You're aware that TVT mesh, the mesh in
13 that device, is heavyweight; right?

14 A. I'm aware it's the -- the predecessor, it's
15 Prolene mesh. I mean, that's -- it came from Prolene
16 mesh.

17 Q. And in terms of the gradation, it's
18 considered a heavyweight mesh; right?

19 A. I don't know that myself personally, no.

20 Q. Are you aware that the Prolene mesh in the
21 TVT is considered a small-pore mesh?

22 MR. SNELL: Foundation.

23 THE WITNESS: No.

24 BY MR. SLATER:

25 Q. Do you know whether or not -- do you know

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1 one way or the other?

2 A. I know it's different than the Ultrapro.

3 That's what I know.

4 Q. Well, Ultrapro --

5 A. And I don't know if it would be categorized
6 as heavyweight mesh.

7 Q. Let me ask you this question: If, in
8 fact, Prolene mesh is known by your company to be a
9 small-pore mesh, your company should not have
10 represented that it had large pores.

11 You would agree with that statement;
12 right?

13 MR. SNELL: Foundation.

14 THE WITNESS: Yes.

15 MR. SLATER: At my peril, I am cutting out
16 about 35 minutes of questions in the hope that your
17 counsel will see the light.

18 MR. SNELL: I just have a few.

19 MR. SLATER: Oh, I do have one more
20 question, and I'm -- and it's mainly for the other
21 attorney who came in the room, who I think will enjoy
22 the question.

23 BY MR. SLATER:

24 Q. You talked about the fact that the
25 advice -- led by Piet Hinoul was Piet Hinoul felt

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1 Prolift is fine, keep it on the market, it's safe and
2 effective; right?

3 A. Yes.

4 Q. Did you ever watch the movie "Animal
5 House"?

6 A. Many years ago.

7 Q. Remember --

8 MS. SCALERA: I'm going to -- I'm going to
9 object.

10 Go ahead.

11 BY MR. SLATER:

12 Q. Do you remember -- do you remember the
13 scene at the end when they disrupt the parade?

14 A. No.

15 Q. Do you remember when Kevin Bacon is the
16 ROTC solder and they disrupt the parade and everybody
17 is in mayhem, running and chaos and fear --

18 A. I don't.

19 Q. -- and he's standing there saying, all is
20 well, everything is fine, all is well?

21 Do you see a parallel between Kevin Bacon
22 in "Animal House" in that scene and Piet Hinoul
23 saying the Prolift was a safe and effective device?

24 A. Well, I don't --

25 MR. SNELL: Hold on. Hold on. Hold on.

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1 Foundation and form. That's argumentative
2 and nonsense.

3 Go ahead.

4 THE WITNESS: I don't know the scene, but
5 I'm sure I would disagree with you.

6 MR. SLATER: Good answer.

7 Now I'm going to hand off the questioning
8 to Mr. Snell. And I -- and I'm saying in all good
9 faith, aside from the kidding around and everything
10 else, I just cut my questioning very short in an
11 effort to try to end this. I'm hoping that counsel
12 will --

13 MR. SNELL: I'm -- I just have a few.

14 MR. SLATER: -- understand that.

15 MR. SNELL: I just have a few.

16 EXAMINATION

17 BY MR. SNELL:

18 Q. Make sure to look at the camera. That's
19 okay.

20 Plaintiffs' counsel just asked you a
21 question about whether the Prolene mesh was
22 macroporous or large-pore mesh.

23 Do you recall that question?

24 A. I do.

25 MR. SLATER: Objection.

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1 BY MR. SNELL:

2 Q. Will you defer to Dr. Piet Hinoul as to
3 whether the Prolene mesh used in TVT is macroporous?

4 A. Yes.

5 Q. I believe you told plaintiffs' counsel, to
6 your knowledge, there wasn't a Prolift clinical study
7 with a primary end point that assessed mesh exposure;
8 correct?

9 MR. SLATER: Objection to the form of the
10 question.

11 MR. SNELL: Did I get that wrong? Because
12 I want to get it right.

13 How about this? I'll take that off the
14 table.

15 BY MR. SNELL:

16 Q. Did Prolift studies assess safety?

17 A. Yes.

18 Q. Did Prolift studies assess complication
19 rates?

20 MR. SLATER: Objection.

21 THE WITNESS: Yes.

22 BY MR. SNELL:

23 Q. Did the risk-benefit analyses, which you
24 have testified to were done multiple times, consider
25 complications?

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1 A. Yes.

2 MR. SLATER: Objection.

3 Just got to give me one beat. I know we
4 all want to get out of here. I've just got to have a
5 chance to object. I'm trying to pack up because I'm
6 one foot out the door right now.

7 BY MR. SNELL:

8 Q. In fact, plaintiffs' counsel pointed you
9 to the November 2010 --

10 A. Yes.

11 Q. -- mesh platform review, for instance, the
12 page on pain. And does that page identify clinical
13 studies that ascertained different safety end points?

14 A. Yes.

15 Q. Plaintiffs' counsel asked you about
16 dyspareunia.

17 Does that page report out of 30 studies
18 that the rate of dyspareunia was 7 percent?

19 MR. SLATER: Objection.

20 THE WITNESS: Yes.

21 BY MR. SNELL:

22 Q. So there's no question -- is there any
23 question in your mind that the Prolift clinical
24 studies analyzed and assessed safety?

25 MR. SLATER: Objection.

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1 THE WITNESS: No.

2 BY MR. SNELL:

3 Q. I just want to make sure it's clear.

4 Regardless of what some testing glass
5 showed regarding an ISO cytotoxicity, what is your
6 opinion, based on your experience and everything
7 you've read about the TVT mesh, as to whether or not
8 it is cytotoxic?

9 MR. SLATER: Objection.

10 THE WITNESS: I don't believe that it's
11 cytotoxic.

12 BY MR. SNELL:

13 Q. And would a cytotoxic mesh perform as well
14 as TVT mesh has performed in over 100 randomized,
15 controlled trials?

16 MR. SLATER: Objection.

17 THE WITNESS: Well, there are obviously
18 gradations of cytotoxicity but a -- a significantly
19 cytotoxic one I would not expect to behave that way
20 or perform that way.

21 BY MR. SNELL:

22 Q. Can -- plaintiffs' counsel asked you about
23 suture erosions.

24 Can there be difficult-to-treat suture
25 erosions?

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1 A. Yes.

2 MR. SLATER: Objection.

3 BY MR. SNELL:

4 Q. Plaintiffs' counsel asked you about the
5 dyspareunia referenced in the Altman 2011 study
6 slide.

7 Do you recall that?

8 A. I do.

9 Q. Just get to it.

10 And that slide, it doesn't say this is the
11 de novo dyspareunia rate, does it?

12 A. Does not.

13 MR. SLATER: Objection.

14 BY MR. SNELL:

15 Q. Does this state that the -- that rate of
16 dyspareunia was de novo?

17 MR. SLATER: Objection.

18 THE WITNESS: Does not.

19 MR. SNELL: Where's the Altman study?

20 MR. SLATER: Gave it back to you.

21 And I want to thank you. I forgot to ask
22 some questions on one of the documents. You never
23 learn, man.

24 I don't have it. I gave it back to you
25 guys.

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1 MR. SNELL: Okay.

2 BY MR. SNELL:

3 Q. Table 4 in the Altman study looks at,
4 among other things, pelvic or genital pain as
5 compared between colporrhaphy and the mesh repair
6 group.

7 Do you see that?

8 MR. SLATER: Objection.

9 THE WITNESS: Yes.

10 BY MR. SNELL:

11 Q. And was there a significant difference
12 between Prolift and the colporrhaphy on pelvic and
13 genital pain?

14 A. Genital pain, no.

15 MR. SLATER: Objection.

16 BY MR. SNELL:

17 Q. Turn to the next page, the longer results,
18 from 2 to 12 months.

19 Was there any difference between Prolift
20 and colporrhaphy in pelvic and genital pain?

21 MR. SLATER: Objection.

22 THE WITNESS: No.

23 BY MR. SNELL:

24 Q. And just for the record, we were looking
25 at the Altman study, Page 8. I'm sorry. Exhibit

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1 858.

2 Plaintiffs' counsel asked you about
3 whether a potential risk of cancer could be excluded
4 at some point way down in the future.

5 Do you recall that question?

6 MR. SLATER: Objection.

7 THE WITNESS: Yes.

8 BY MR. SNELL:

9 Q. Do the current data show a link between
10 polypropylene, Prolene polypropylene mesh, and
11 cancer?

12 MR. SLATER: Objection.

13 THE WITNESS: No.

14 BY MR. SNELL:

15 Q. Are sarcomas the same as carcinomas?

16 A. No.

17 Q. Are you an oncologist?

18 A. No.

19 Q. Are you a gynecologic pathologist who has
20 particular expertise in gynecologic cancer?

21 A. No.

22 MR. SLATER: I don't know why you're
23 smirking at me. I've been talking to women with
24 bladder cancer, so I wouldn't be laughing so hard.

25 MR. SNELL: I'm not smirking at you.

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1 MR. SLATER: Yeah. Well, it's not funny.

2 MR. SNELL: What are you talking about?

3 I'm not smirking at you.

4 MR. SLATER: Just don't play gotcha games
5 when you're talking about cancer. Okay? There's a
6 lot of women out there with pelvic cancers.

7 MS. SCALERA: I think we should strike
8 that entirely.

9 MR. SLATER: You know what? You're not a
10 part of this deposition. We don't need your input,
11 please.

12 MR. SNELL: We can strike it.

13 MR. SLATER: You walk in after nine or ten
14 hours and start talking? Please.

15 MS. SCALERA: I'm an attorney in this
16 case --

17 MR. SLATER: I don't care. We didn't --

18 MS. SCALERA: -- and I'm saying that you
19 should strike that from the record, but that's up to
20 you.

21 MR. SLATER: It's not being stricken from
22 the record.

23 MR. SNELL: It will be stricken because
24 it's attorney comment, it's not testimony nor is it a
25 question.

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1 MR. SLATER: There's nothing to strike.

2 Could you just continue, please? Some
3 minimal level of competency in this room, and let's
4 get going.

5 BY MR. SNELL:

6 Q. And what may or may not be seen in a rat
7 upon solid-state insertion of a disk is not
8 transferrable to humans; is that correct or not?

9 MR. SLATER: Objection.

10 THE WITNESS: That's my understanding.

11 BY MR. SNELL:

12 Q. Plaintiffs' counsel asked you whether the
13 cytotoxicity or the certain ISO tests were ever
14 disclosed to the FDA.

15 My question to you is, were they?

16 MR. SLATER: Objection.

17 THE WITNESS: Yes.

18 BY MR. SNELL:

19 Q. You've seen the 510(k) for the TVT.

20 Did Ethicon disclose the cytotoxicity test
21 results to the FDA?

22 A. Yes.

23 Q. They did that way back before the FDA --
24 strike that.

25 Was that done before the FDA cleared TVT?

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1 MR. SLATER: Objection.

2 THE WITNESS: Yes.

3 MR. SNELL: All right.

4 Thanks. No further.

5 EXAMINATION

6 BY MR. SLATER:

7 Q. Are you aware that in the 510(k) process
8 the FDA is not assessing safety and effectiveness,
9 and is only assessing substantial equivalence to the
10 predicate device?

11 MR. SNELL: Foundation.

12 THE WITNESS: As -- as can be evidenced by
13 performance in some cases, yes, I am aware.

14 BY MR. SLATER:

15 Q. In the Altman study on Page 1832, lower
16 right-hand part of the page --

17 A. I need it back.

18 Q. -- it points out that in assessing pain
19 with intercourse, 2 percent of the women with
20 colporrhaphy had pain with intercourse, 7.3 percent
21 had pain with intercourse with -- where they had mesh
22 put in their body, the Prolift in their body;
23 correct?

24 MR. SNELL: Why don't you get the paper
25 out. That misstates. Foundation.

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1 THE WITNESS: I think -- I think you have
2 it.

3 MR. SNELL: Oh, I have it here. Give it
4 to him. Because you're leaving out things.

5 MR. SLATER: You know what?

6 MR. SNELL: Hold on. Altman. I think I
7 might have stuck it under here.

8 There you go.

9 MR. SLATER: Give me the article.

10 MR. SNELL: Yeah.

11 No foundation, misstates the document.

12 BY MR. SLATER:

13 Q. I'm going to read something and hand it to
14 you, okay, because we only have one copy?

15 On Page 1832 of the Altman study, in
16 talking about pain with intercourse it says, pain
17 during sexual intercourse was reported to occur
18 usually or always by 2 percent of the women after
19 colporrhaphy and by 7.3 percent after transvaginal
20 mesh surgery.

21 MR. SNELL: Let me see that.

22 BY MR. SLATER:

23 Q. That's reported in the lower right-hand
24 corner.

25 You can tell me if that's a correct

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1 reading of what was reported on that specific topic.

2 MR. SNELL: Can you read back his
3 question? I just want to make sure that he said --

4 MR. SLATER: Why don't you give it to the
5 witness and let him read along --

6 MR. SNELL: Okay.

7 MR. SLATER: -- since he's, by far, the
8 smartest person in the room.

9 MR. SNELL: I just want to make sure you
10 included the usually or always.

11 MR. SLATER: Keep making sure.

12 MR. SNELL: Can you read back his
13 question?

14 THE WITNESS: His question was, did I read
15 that correctly?

16 MR. SNELL: No. No. But I want to know
17 if he read it correctly.

18 THE WITNESS: Oh. Oh. Oh.

19 MR. SNELL: You should read along while
20 she repeats his question.

21 BY MR. SLATER:

22 Q. How about this? Do me a favor: The
23 phrase that I just read, can you read it for the
24 record, what the article says about pain with
25 intercourse?

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1 A. When we analyzed individual outcomes that
2 might be affected differently after the two types of
3 interventions, pain during sexual intercourse was
4 reported to occur usually or always by 2 percent of
5 the women after colporrhaphy and by 7.3 percent after
6 trans-mesh -- transvaginal mesh surgery, P equals
7 .07.

8 Q. Okay. Thank you.

9 Now, do you have the -- the License and
10 Supply Agreement with Medscand?

11 A. Somewhere.

12 Q. This is what I forgot to ask you about
13 before but while counsel was questioning you I found
14 it in a pile and now I have to ask you a couple of
15 questions that never would have been asked if counsel
16 had just stopped.

17 A. I have it.

18 Q. There you go.

19 Let me ask you --

20 MR. SNELL: Let me get there real quick.

21 Go ahead.

22 BY MR. SLATER:

23 Q. Okay. I'm now asking you about the
24 License and Supply Agreement with Medscand that
25 counsel asked you about a few moments ago.

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1 MR. SNELL: Just let me get to it real
2 quick, Adam.

3 Okay. Thank you.

4 BY MR. SLATER:

5 Q. In looking at the License and Supply
6 Agreement with Medscand that counsel asked you about
7 a few moments ago, this is a contract between Johnson
8 & Johnson and Medscand Medical and it -- and it deals
9 with the terms and conditions under which the device
10 or the procedure that was the prototype for the TVT
11 would be transferred to the ownership of Johnson &
12 Johnson; right?

13 MR. SNELL: Form.

14 THE WITNESS: Yeah. I'm not sure what's
15 the difference between license and acquisition, but
16 yeah.

17 MR. SLATER: Beats me.

18 BY MR. SLATER:

19 Q. Let me ask you what I wanted to get to.
20 Okay?

21 Counsel asked you if milestone payments
22 are common in these types of agreements and you said
23 yeah; right?

24 A. I did.

25 Q. Is it common for milestone payments to be

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1 tied directly to whether or not adverse events are
2 reported in the study?

3 A. So I'm certainly aware of instances where
4 in licensing agreements -- whoops -- milestone
5 payments are agreed to or agreed upon depending upon
6 certain outcomes from clinical research and could
7 include establishment of health authority approval or
8 clearance or whatever, yeah.

9 Q. Well --

10 A. So it certainly can depend on clinical
11 outcome.

12 Q. In this Agreement the milestone payments
13 were contingent on the results of the clinical trials
14 will be considered acceptable if, first, they do not
15 differ significantly from the results published in
16 the original article published in the International
17 Urogynecology Journal in 1996 by Dr. Ulmsten, et al.,
18 regarding the following items, and then lists safety,
19 efficacy, long-term results and intraoperative
20 complications or procedural -- procedure-related
21 complications.

22 See that?

23 MR. SNELL: Form and foundation.

24 THE WITNESS: Where is it?

25 MR. SLATER: It's on -- it says 996, the

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1 last three digits.

2 MR. SNELL: Form and foundation.

3 Adam, I think you said the milestone,
4 plural. Milestone.

5 MR. SLATER: I'll ask the question again.

6 MR. SNELL: I just want to make sure you
7 clean it up.

8 MR. SLATER: It's fine.

9 MR. SNELL: I think you said milestone.
10 Because you know there's three of them. That's my
11 foundation.

12 BY MR. SLATER:

13 Q. Exhibit C presents the criteria for the
14 \$400,000 milestone payment to be paid.

15 Do you see Exhibit C?

16 A. I do.

17 Q. And that was tied directly to the results
18 being considered acceptable, and that's defined as
19 not differing significantly from the results
20 published in the original article published by Dr.
21 Ulmsten in 1996; right?

22 A. Right.

23 Q. And then it talks about the items that are
24 actually captured within that category includes
25 postoperative complications like infection and/or

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1 rejection of the material, defect healing, slight
2 postoperative voiding problems and chronic voiding
3 problems.

4 Do you see that?

5 A. I do.

6 Q. And then there's some efficacy statements,
7 long-term results and procedural-related
8 complications.

9 All of those were conditions that had to
10 be met that there would be no significantly different
11 frequency or severity of those complications; right?

12 A. Right.

13 Q. Therefore, there was a significant
14 incentive for the investigators not to report such
15 findings because that would have caused them not to
16 get \$400,000; right?

17 MR. SNELL: Foundation.

18 THE WITNESS: So in any of these licensing
19 agreements when you have a milestone that's based on
20 a clinical outcome, it's -- it's incumbent upon those
21 of us that are paying for the product and the product
22 becomes more valuable when -- when studies are
23 corroborated.

24 So I know for sure this -- the intent here
25 was to say, is this reproducible outside of one

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1 person's hands and is there incentive for them to --
2 say that -- so say the question again. I'm sorry. I
3 forget the words.

4 BY MR. SLATER:

5 Q. The incentive is to not report
6 complications or adverse events that would cause that
7 milestone payment not to be paid under Exhibit C.

8 A. Which would be an egregious breach of good
9 clinical practice.

10 Q. Yes, it would, wouldn't it?

11 A. It would be incumbent upon the company
12 that's paying the money to -- to have visibility to
13 how the data were collected and so forth.

14 Q. Do you know whether your company actually
15 even looked at the data?

16 A. I don't know. I wasn't -- no.

17 Q. In this type of a situation it would be
18 incumbent on Johnson & Johnson to actually, when you
19 say have visibility to the data, to look at the
20 actual patient-level data to make sure it's being
21 accurately reported; right?

22 MR. SNELL: Foundation.

23 Go ahead.

24 THE WITNESS: They have some level of due
25 diligence that -- that they would undertake to

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1 understand the -- the integrity of the data. I
2 don't -- I don't know what they -- you know, what
3 level that was.

4 BY MR. SLATER:

5 Q. If nothing was done to directly evaluate
6 the integrity of the data, that would be a problem;
7 right?

8 MR. SNELL: Foundation.

9 THE WITNESS: Yeah, I -- I just believe,
10 again, that the -- the paying company, it's --
11 it's -- it's -- it's -- they need -- they need to
12 have the satisfaction that the data represents what
13 happened in the trial because they're paying for it.
14 I mean, they're -- they're -- they need the data to
15 be good.

16 BY MR. SLATER:

17 Q. When you say good, you mean valid; right?

18 A. Yeah, that -- yeah.

19 Q. And you need to confirm it's valid
20 independently; right?

21 A. You need to be assured of it in your own
22 mind, yes.

23 MR. SLATER: I don't have any other
24 questions.

25 EXAMINATION

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1 BY MR. SNELL:

2 Q. Was Ulmsten's study data confirmed time
3 and time again in numerous clinical studies in these
4 documents plaintiffs' counsel has shown to you?

5 MR. SLATER: Objection.

6 THE WITNESS: Yes.

7 MR. SNELL: No further questions.

8 VIDEO OPERATOR: The time is now 8:53.

9 This is the end of Disk Number 6. This
10 concludes today's deposition.

11 We are going off the record.

12 (Whereupon the deposition concluded at
13 8:53 p.m.)

14 TESTIMONY CLOSED

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1 CERTIFICATE

2

3 I HEREBY CERTIFY that the witness was duly
4 sworn by me and that the deposition is a true record
5 of the testimony given by the witness.

6 It was requested before completion of the
7 deposition that the witness, JAMES C. HART, M.D.,
8 have the opportunity to read and sign the deposition
9 transcript.

10

11

12

13

ROSEMARY LOCKLEAR

REGISTERED PROFESSIONAL REPORTER

14

CERTIFIED COURT REPORTER (NJ)

30XI00171000

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CERTIFIED REALTIME REPORTER

NOTARY PUBLIC

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Dated: 01/09/2014

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(The foregoing certification of this
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same by any means, unless under the direct control
and/or supervision of the certifying reporter.)

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1 INSTRUCTIONS TO WITNESS

2

3

4 Please read your deposition over carefully
5 and make any necessary corrections. You should state
6 the reason in the appropriate space on the Errata
7 Sheet for any corrections that are made.

8 After doing so, please sign the Errata
9 Sheet and date it.

10 You are signing same subject to the
11 changes you have noted on the Errata Sheet, which
12 will be attached to your deposition.

13 It is imperative that you return the
14 original Errata Sheet to the deposing attorney within
15 thirty (30) days of receipt of the deposition
16 transcript by you. If you fail to do so, the
17 deposition transcript may be deemed to be accurate
18 and may be used in court.

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1 E R R A T A

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22 REASON: _____

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1 ACKNOWLEDGEMENT OF DEPONENT

2

3

4 I, _____, do hereby
5 certify that I have read the foregoing pages, and
6 that the same is a correct transcription of the
7 answers given by me to the questions therein
8 propounded, except for the corrections or changes in
9 form or substance, if any, noted in the attached
10 Errata Sheet.

11

12

13

14 _____

15 JAMES C. HART, M.D.

DATE

16

17 Subscribed and sworn

18 to before me this

19 _____ day of _____, 20____.

20

My commission expires:_____

21

22 _____

Notary Public

23

24

25

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1	LAWYER'S NOTES		
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